UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report: Not applicable

For the transition period from ____ to _____

Commission file number 001-35948

Kamada Ltd.
(Exact name of registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

State of Israel
(Jurisdiction of incorporation or organization)

2 Holzman St.
Science Park
P.O Box 4081
Rehovot 7670402
Israel
(Address of principal executive offices)

Amir London, Chief Executive Officer
2 Holzman St., Science Park
Rehovot 7670402, Israel
+972 8 9406472
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of Each Class	Name of Each Exchange on which Registered
Ordinary Shares, par value NIS 1.00 each	The Nasdaq Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act. **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

As of December 31, 2020, the Registrant had 44,742,963 Ordinary Shares outstanding.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer", "accelerated filer", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐	International Financial Reporting Standards as issued by the International Accounting Standards Board ☒	Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

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In this Annual Report on Form 20-F (this "Annual Report"), unless the context indicates otherwise, references to "NIS" are to the legal currency of Israel, "U.S. dollars," "$" or "dollars" are to United States dollars, and the terms "we," "us," the "Company," "our company," "our," and "Kamada" refer to Kamada Ltd., along with its consolidated subsidiaries.

This Annual Report contains forward-looking statements that relate to future events or our future financial performance, which express the current beliefs and expectations of our management in light of the information currently available to it. Such statements involve a number of known and unknown risks, uncertainties and other factors that could cause our actual future results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Forward-looking statements include all statements that are not historical facts and can be identified by words such as, but without limitation, "believe," "expect," "anticipate," "estimate," "intend," "plan," "target," "likely," "may," "will," "would," or "could," or other words, expressions or phrases of similar substance or the negative thereof. We have based these forward-looking statements largely on our management's current expectations and future events and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. Forward-looking statements include, but are not limited to, statements about:

- *our expectation that Takeda Pharmaceutical Company Limited ("Takeda") will complete the technology transfer of Alpha-1 Antitrypsin ("AAT") intravenous product, GLASSIA® ("GLASSIA"), and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021 and that accordingly, we anticipate that sales of GLASSIA to Takeda during 2021 will be reduced to approximately $25 million, as compared to $64.9 million during 2020;*

- *our expectation that the reduction in GLASSIA sales to Takeda during 2021 (as mentioned above), and the higher levels of inventory of our proprietary products at our distributers (including that of our anti-rabies immunoglobulin products, KEDRAB® ("KEDRAB") at Kedrion S.p.A ("Kedrion") as well as our commercial products at our Israeli customers, and our expectation that the continued effect of change in product sales mix during 2021, as well as reduced plant utilization are anticipated to result in a reduction in revenues and profitability in 2021;*

- *our intention to expand our Proprietary plasma-derived products business by maximizing the market potential of our existing Proprietary products portfolio;*

- *our intention to broadening our Distribution products portfolio, with a focus on biosimilar products;*

- *our intention to enhance our current manufacturing capabilities, and to evolve into a vertically integrated plasma-derived company;*

- *our plan to continue to develop our pipeline, primarily focusing on the pivotal Phase 3 InnovAATe clinical trial of Inhaled AAT for the treatment of Alpha-1 Antitrypsin Deficiency ("AATD") and the development of our Anti-SARS-CoV-2 IgG product, and to explore new strategic business development opportunities.*

- *our intention, in a post-COVID-19 era, to leverage our expertise in plasma-derived protein therapeutics in order to address unmet medical needs in potential future emerging healthcare pandemic or epidemic crises, and to establish a holistic IgG readiness offering and identify additional opportunities in complementary pandemic-related treatment solutions;*

- *our expectation that the financial impact of the COVID-19 pandemic cannot be reasonably estimated at this time but may materially affect our business, financial condition and results of operation, and that the full extent to which the pandemic impacts our business and financial results will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity and duration of the pandemic and actions to contain its spread or treat its impact, among others;*

- *our expectation that the reduced plant utilization as well as the expected change in product sales mix, driven by the expected reduction in sales of GLASSIA to Takeda, will result in a continued decrease in the Propriety Products segment's full-year gross margins for 2021;*

- *our intent to leverage our experience and available manufacturing capacity at our FDA-approved manufacturing facility to initiate the production of additional plasma-derived products following the transition of GLASSIA manufacturing to Takeda during 2021 through acquisitions or provision of CMO services;*

- *our expectation that following the completion of the currently on-going technology transfer process, and pending receipt of all required FDA approvals, we will commence commercial manufacturing in early 2023 of an FDA-approved and commercialized specialty hyper-immune globulin product with respect to which we entered into a binding term sheet for a 12-year contract manufacturing agreement in December 2019;*

- *our estimation, based on the current market sales volume of this specialty hyper-immune globulin product, that its manufacturing opportunity will add approximately $8 million to $10 million to our annual revenues, with estimated gross margin level similar to the average gross margins of our Proprietary Products segment;*

- *our expectation that the recent agreement entered into with respect to the acquisition of the plasma collection center of Blood and Plasma Research, Inc. ("B&PR") in Beaumont, Texas, which represents our entry into the U.S. plasma collection market, shall further our strategic goal of becoming a fully integrated specialty plasma company;*

- *our plan, following the closing of the acquisition of the B&PR plasma collection center in Beaumont, Texas, to significantly expand our hyperimmune plasma collection capacity by investing in the center, and to leverage its FDA license to open additional centers in the United States;*

- *our expectation that upon initiation of sales of GLASSIA manufactured by Takeda, Takeda will pay us royalties at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040, and our expectation that based on current GLASSIA sales in the United States and forecasted future growth, we will receive royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040;*

- *our expectation to supply during the first months of 2021, to the Israel Ministry of Health ("IMOH"), pursuant to an agreement entered into during October 2020, such quantities of our investigational Anti-SARS-CoV-2 IgG product to treat approximately 500 hospitalized COVID-19 patients in Israel, and that this initial supply is expected to generate approximately $3.4 million in revenue in 2021;*

- *our anticipation, based on discussions with the IMOH, that the treatment utilizing our investigational Anti-SARS-CoV-2 IgG product will be provided as part of a multi-center clinical study initiated by the IMOH;*

- *our plans to ramp up our investigational Anti-SARS-CoV-2 IgG manufacturing capacity, and our intention to increase our supply capabilities during 2021 to support potential additional demand from the IMOH, and possibly other international markets;*

- *our belief that our current cash and cash equivalents and short-term investments will be sufficient to satisfy our liquidity requirements for the next 12 months;*

- *our belief that our relationships with our strategic partners, including with Takeda and Kedrion, will continue without disruption;*

- *our belief that we will be able to register our proprietary products in additional countries where they are not currently registered, and our belief that this would lead to additional sales worldwide;*

- *our belief that we will be able to continue to meet our customers demand for GLASSIA, KEDRAB, and other proprietary products;*

- *our expectation that sales of KamRAB through the Pan American Health Organization ("PAHO"), as well as in Canada and other markets will continue in 2021;*

- *our estimation that the total U.S. market for rabies treatment is approximately $150 million per year and our expectation that our market share for KEDRAB sales in the U.S. market will continue to grow in the coming years;*

- *our belief that U.S.-based and other healthcare providers would seek to continue to diversify their source of anti-rabies immunoglobulin using our product;*

- *our belief that anti-rabies products based on equine serum are inferior to products made from human plasma;*

- *our expectations regarding the potential market opportunities for our products and product candidates;*

- *our expectations regarding the potential actions or inactions of existing and potential competitors of our products, including our belief that there will be no new supplier of AAT by infusion in the U.S. market in the near future;*

- *the legislation or regulation in countries where we sell our products that affect product pricing, reimbursement, market access or distribution channels may affect our sales and profitability;*

- *our projection that changes in the product sales mix and geographic sales mix may have an effect on our sales and profitability;*

- *our ability to procure adequate quantities of plasma and fraction IV from our suppliers, which are acceptable for use in our manufacturing processes;*

- *our ability to maintain compliance with government regulations and licenses;*

- *our expectation of launching Bonsity in Israel during 2022 upon receipt of regulatory approval from the IMOH;*

- *our expectation of launching five other biosimilar products pursuant to an agreement with Alvotech and three other biosimilar products during the years 2022 to 2025, subject to approval by the European Medicines Agency ("EMA") and subsequent approval by IMOH;*

- *our estimation that the potential aggregate maximum revenues, achievable within several years of launch, generated by the distribution of all nine biosimilar products to be in the range of $25 million to $35 million annually;*

- *our ability to identify growth opportunities for existing products and our ability to identify and develop new product candidates;*

- *our plan to continue to evaluate the best suitable plan for the U.S. and/or EU Anti-SARS-CoV-2 IgG clinical program, and that we will advance the development of the product upon the conclusion of this review;*

- *our expectation that the final results from a Phase 1/2 open-label, single-arm, multi-center clinical trial in Israel of our Anti-SARS-CoV-2 IgG product will be available during the first quarter of 2021;*

- *our belief that the market opportunity for AAT products will continue to grow;*

- *our ability to attract partners for development programs for Inhaled AAT for AATD in the United States and the European Union, and to maintain such partnerships, if we decide to pursue such direction, as well as the impact on our business resulting from such partnerships, or from a failure to form such partnerships or fully realize the benefits of such partnerships;*

- *our belief that Inhaled AAT for AATD will increase patient convenience and reduce the need for patients to use intravenous infusions of AAT products, thereby decreasing the need for clinic visits or nurse home visits and reducing medical costs;*

- *our belief that Inhaled AAT for AATD will enable us to treat significantly more patients from the same amount of fraction IV and production capacity and therefore increase our profitability;*

- *our ability to, obtain and/or maintain regulatory approvals for our products and new product candidates, the rate and degree of market acceptance, and the clinical utility of our products;*

- *our development plan of a recombinant AAT product and its future potential utilization;*

- *our ability to obtain and maintain protection for the intellectual property, trade secrets and know-how relating to or incorporated into our technology and products;*

- *our expectations regarding our ability to utilize Israeli tax incentives against future income; and*

- *our expectations regarding taxation, including that we will not be classified as a passive foreign investment company for the taxable year ending December 31, 2021.*

All forward-looking statements involve risks, assumptions and uncertainties. You should not rely upon forward-looking statements as predictors of future events. The occurrence of the events described, and the achievement of the expected results, depend on many events and factors, some or all of which may not be predictable or within our control. Actual results may differ materially from expected results. See the sections "Item 3. Key Information — D. Risk Factors" and "Item 5. Operating and Financial Review and Prospectus," as well as elsewhere in this Annual Report, for a more complete discussion of these risks, assumptions and uncertainties and for other risks, assumptions and uncertainties. These risks, assumptions and uncertainties are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results.

All of the forward-looking statements we have included in this Annual Report are based on information available to us as of the date of this Annual Report and speak only as of the date hereof. We undertake no obligation, and specifically decline any obligation, to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Annual Report might not occur.

The audited consolidated financial statements for the years ended December 31, 2020, 2019 and 2018 included in this Annual Report have been prepared in accordance with the international financial reporting standards ("IFRS") as issued by the international accounting standards board ("IASB"). None of the financial information in this Annual Report has been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

Unless otherwise noted, NIS amounts presented in this Annual Report are translated at the rate of $1.00 = NIS 3.215, the exchange rate published by the Bank of Israel as of December 31, 2020.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. Selected Financial Data

The following table summarizes our consolidated financial data. We have derived the summary consolidated statements of operations data for the years ended December 31, 2020, 2019 and 2018 and the consolidated balance sheets data as of December 31, 2020 and 2019 from our audited consolidated financial statements included elsewhere in this Annual Report. We have derived the summary consolidated statements of operations data for the years ended December 31, 2017 and 2016 and the summary consolidated balance sheet data as of December 31, 2018, 2017 and 2016 from our audited consolidated financial statements not included in this Annual Report.

We have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those summary consolidated statements. Our historical results are not necessarily indicative of the results that should be expected in the future, and our interim results are not necessarily indicative of the results that should be expected for the full year.

The summary of our consolidated financial data set forth below should be read together with our consolidated financial statements and the related notes, as well as the section entitled "Item 5. Operating and Financial Review and Prospects," included elsewhere in this Annual Report.

	Year Ended December 31,				
	2020	2019	2018	2017	2016
	(U.S. Dollars in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues from Proprietary Products	$ 100,916	$ 97,696	$ 90,784	$ 79,559	$ 55,958
Revenues from Distribution	32,330	29,491	23,685	23,266	21,536
Total revenues	133,246	127,187	114,469	102,825	77,494
Cost of revenues from Proprietary Products	57,750	52,425	52,796	51,335	37,723
Cost of revenues from Distribution	27,944	25,025	20,201	19,402	18,411
Total cost of revenues	85,694	77,450	72,997	70,737	56,134
Gross profit	47,552	49,737	41,472	32,088	21,360
Research and development expenses	13,609	13,059	9,747	11,973	16,245
Selling and marketing expenses	4,518	4,370	3,630	4,398	3,243
General and administrative expenses	10,139	9,194	8,525	8,273	7,353
Other expense	49	330	311	-	-
Operating income (loss)	19,237	22,784	19,259	7,444	(5,481)
Financial income	1,027	1,146	830	500	470
Income (expense) in respect of securities measured at fair value, net	102	(5)	(178)	(80)	(13)
Income (expense) in respect of currency exchange and translation differences and derivatives instruments, net	(1,535)	(651)	602	(612)	127
Financial expense	(266)	(293)	(172)	(82)	(114)
Income (loss) before taxes on income	18,565	22,981	20,341	7,170	(5,011)
Taxes on income	1,425	730	(1,955)	269	1,722
Net income (loss)	17,140	22,251	22,296	6,901	(6,733)
Income (loss) attributable to equity holders	17,140	22,251	22,296	6,901	(6,733)
Income (loss) per share attributable to equity holders:					
Basic	$ 0.39	$ 0.55	$ 0.55	$ 0.18	$ (0.18)
Diluted	$ 0.38	$ 0.55	$ 0.55	$ 0.18	$ (0.18)
Weighted-average number of ordinary shares used to compute income (loss) per share attributable to equity holders:					
Basic	40,140,771	40,320,888	40,275,374	37,970,697	36,418,833
Diluted	44,589,878	40,581,627	40,445,417	38,045,097	36,418,833
Consolidated Statements of Cash Flows:					
Cash flows from operating activities	$ 19,105	$ 27,571	$ 10,546	$ 3,608	$ 1,897
Cash flows from investing activities	(13,127)	(564)	(5,176)	(15,608)	1,637
Cash flows from financing activities	23,364	(1,530)	(587)	15,320	1,490
Consolidated Balance Sheet Data:					
Cash, cash equivalents, restricted cash and short-term investments	$ 100,266	$ 73,907	$ 50,592	$ 43,019	$ 28,632
Trade receivables	22,108	23,210	27,674	30,662	19,788
Working capital [1]	152,947	110,823	87,321	67,486	49,871
Total assets	210,665	173,797	138,116	122,110	99,696
Total liabilities	32,027	38,478	25,740	32,618	32,953
Total shareholders' equity	178,638	135,319	112,376	89,492	66,743
Number of outstanding ordinary shares	44,742,963	40,353,101	40,295,078	40,262,819	36,447,175
Other Data:					
Adjusted net income (loss)[2] [3]	$ 18,117	$ 23,414	$ 23,244	$ 7,384	$ (5,663)
Adjusted EBITDA[2]	$ 25,111	$ 28,466	$ 23,910	$ 11,450	$ (909)

(1) Working capital is defined as total current assets minus total current liabilities.

(2) We present adjusted net income (loss) and adjusted EBITDA because we use these non-IFRS financial measures to assess our operational performance, for financial and operational decision-making, and as a means to evaluate period-to-period comparisons on a consistent basis. Management believes these non-IFRS financial measures are useful to investors because: (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making; and (2) they exclude the impact of non-cash items that are not directly attributable to our core operating performance and that may obscure trends in the core operating performance of the business.

Non-IFRS financial measures have limitations as an analytical tool and should not be considered in isolation from, or as a substitute for, our IFRS results. We expect to continue reporting non-IFRS financial measures, adjusting for the items described below, and we expect to continue to incur expenses similar to certain of the non-cash, non-IFRS adjustments described below. Accordingly, unless otherwise stated, the exclusion of these and other similar items in the presentation of non-IFRS financial measures should not be construed as an inference that these items are unusual, infrequent or non-recurring. Adjusted net income (loss) and adjusted EBITDA are not recognized terms under IFRS and do not purport to be an alternative to IFRS net income (loss) as an indicator of operating performance or any other IFRS measure. Moreover, because not all companies use identical measures and calculations, the presentation of adjusted net income (loss) or adjusted EBITDA may not be comparable to other similarly titled measures of other companies.

Adjusted net income (loss) is defined as net income (loss), plus non-cash share-based compensation expenses. Our management believes that excluding non-cash charges related to share-based compensation provides useful information to investors because of its non-cash nature, varying available valuation methodologies among companies and the subjectivity of the assumptions and the variety of award types that a company can use under the relevant accounting guidance, which may obscure trends in our core operating performance.

(3) Adjusted EBITDA is defined as net income (loss), plus income tax expense, plus or minus financial income or expenses, net, plus or minus income or expense in respect of securities measured at fair value, net, plus or minus income or expenses in respect of currency exchange differences and derivatives instruments, net, plus depreciation and amortization expense, plus non-cash share-based compensation expenses. Management believes that adjusted EBITDA provides useful information to investors for the same reasons discussed above for adjusted net income (loss).

The following tables set forth adjusted net income (loss) and adjusted EBITDA and also reconcile these figures to the IFRS measure net income (loss):

	Year Ended December 31,				
	2020	**2019**	**2018**	**2017**	**2016**
	(U.S. Dollars in thousands)				
Net income (loss)	$ 17,140	$ 22,251	$ 22,296	$ 6,901	$ (6,733)
Non-cash share-based compensation expenses	977	1,163	948	483	1,071
Adjusted net income (loss)	$ 18,117	$ 23,414	$ 23,244	$ 7,384	$ (5,663)

	Year Ended December 31,				
	2020	**2019**	**2018**	**2017**	**2016**
	(U.S. Dollars in thousands)				
Net income (loss)	$ 17,140	$ 22,251	$ 22,296	$ 6,901	$ (6,733)
Income tax expense	1,425	730	(1,955)	269	1,722
Financial expense, net	672	(197)	(1,082)	274	(470)
Depreciation and amortization expense	4,897	4,519	3,703	3,523	3,501
Non-cash share-based compensation expenses	977	1,163	948	483	1,071
Adjusted EBITDA	$ 25,111	$ 28,466	$ 23,910	$ 11,450	$ (909)

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report, including the consolidated financial statements and the related notes included elsewhere in this Annual Report. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected.

Risks Related to Our Business

Our business is currently highly concentrated on our two leading products, GLASSIA and KEDRAB, and in our largest geographic region, the United States. Any adverse market event with respect to such products or the United States would have a material adverse effect on our business (see next risk factor for the effect of transition of GLASSIA manufacturing to Takeda in 2021).

We rely heavily upon the sales of GLASSIA, our AAT intravenous product, and KEDRAB, the post-exposure prophylactic treatment of rabies. Revenue from these products comprised approximately 53%, 58% and 60% and 14%, 13% and 10%, respectively, of our total revenues for the years ended December 31, 2020, 2019 and 2018, respectively.

With respect to a reduction in sales of GLASSIA due to the transfer of GLASSIA manufacturing to Takeda see "*—With the cessation of production of GLASSIA for Takeda in 2021, our revenues and profitability will decrease."* If KEDRAB were to lose significant sales, or were to be substantially or completely displaced in the market, we would lose a significant and material source of our total revenues. Similarly, if these products were to become the subject of litigation and/or an adverse governmental ruling requiring us to cease the manufacturing, export or sales of these products, our business would be adversely affected.

We also rely heavily on sales in the United States, which comprised approximately 63%, 66% and 66% of our total revenues for the years ended December 31, 2020, 2019 and 2018, respectively. If our U.S. sales were significantly impacted by material changes to government or private payor reimbursement, other regulatory developments, competition or other factors, then our business would be adversely affected.

With the cessation of production of GLASSIA for Takeda in 2021, our revenues and profitability will decrease.

We have a partnership arrangement with Takeda, pursuant to which Takeda is the sole distributor of GLASSIA in the United States, Canada, Australia and New Zealand. The partnership agreement was originally executed in 2010 with Baxter International Inc. ("Baxter"). During 2015, Baxter assigned all its rights under the partnership agreement to Baxalta U.S. Inc. ("Baxalta"), an independent public company which spun-off from Baxter. In 2016, Shire plc ("Shire") completed its acquisition of Baxalta, and as a result, all of Baxalta's rights under the partnership agreement were assigned to Shire. In January 2019, Takeda completed its acquisition of Shire.

In 2021, Takeda will complete the technology transfer of GLASSIA, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market. After this transition, Takeda has no obligation to purchase any amount of GLASSIA from us. Based on our agreement with Takeda, we anticipate that sales of GLASSIA to Takeda during 2021 will be reduced to approximately $25 million, as compared to $64.9 million during 2020, which is Takeda's minimum commitment for 2021 pursuant to our existing agreement. Based on the agreement between the companies, upon initiation of sales of GLASSIA manufactured by Takeda, it will pay royalties to us at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040. Based on current GLASSIA sales in the United States and forecasted future growth, we project receiving royalties from Takeda in the range of $10 million to $20 million per year from 2022 to 2040. The transition of GLASSIA manufacturing to Takeda and the transition of the agreement to its royalties phase will result in a significant reduction of our revenue and profitability.

We may have excess manufacturing plant capacity in our manufacturing facility, which may result in significant reduction in operating profits.

Our revenues will decrease and our operating results may be materially and adversely impacted if we are unable to continue operating our manufacturing facility at its current capacity and/or level of profitability, or otherwise to reduce direct and indirect costs relating to our manufacturing facility in line with any reduction in demand or manufacturing level.

Following the transition of GLASSIA manufacturing to Takeda, we may be affected by reduced efficiency of our manufacturing facility, which may cause us to incur increased manufacturing costs per vial, reduced gross profitability and potential operating losses. We plan to utilize the excess manufacturing capacity in our manufacturing plant to support the growth of our other existing proprietary products. While we are capable of manufacturing more of these products, there is no assurance that there will be increased market demand for these products in the currently existing markets in which we distribute our products or other markets. The manufacturing of excess quantities of products, which may not be sold due to lower demands, may result in the need to write-down the value of inventories which may result in significant operating losses.

The reduced plant utilization as well as the expected change in product sales mix driven by the expected reduction in sales of GLASSIA to Takeda, is anticipated to result in a continued decrease in the Propriety Products segment's full-year gross margins.

We believe the risk of not adequately adjusting to lower plant utilization could result in inefficiencies, reduced profitability or operating losses. In addition, these changes may require significant layoffs, which may be expensive and may lead to labor issues and strikes, which could affect our ability to continue to manufacture products and may lead to increase costs, reduced profitability and operating losses. For labor related risk see "*—We have entered into a collective bargaining agreement with the employees' committee and the Histadrut (General Federation of Labor in Israel), and we have incurred and could in the future incur labor costs or experience work stoppages or labor strikes as a result of any disputes in connection with such agreement."*

Manufacturing of new plasma-derived products in our manufacturing facility requires a lengthy and challenging development project and/or technology transfer project as well as regulatory approvals, all of which may not materialize.

We are exploring opportunities to manufacture in our manufacturing plant other new plasma-derived products that we have not previously manufactured.

The manufacturing of other marketed or investigational plasma-derived products in our plant, including, our Anti-SARS-CoV-2 IgG investigational product as a potential treatment for COVID-19 and the hyper-immune globulin product for which we executed a 12-year contract manufacturing agreement with an undisclosed partner, requires a lengthy and challenging development project and/or technology transfer project through which we transfer the know-how and capabilities to manufacture the new product. Such projects are usually complex and involve investment of significant time (approximately two to four years) and resources. There is no assurance that such development and/or technology transfer projects will be successful and will allow us to manufacture the new product according to its required specifications.

Such development and/or technology transfer projects require regulatory approval by the FDA and/or EMA or other relevant regulatory agencies. Obtaining such regulatory approval may require activities such as the manufacturing of comparable batches and/or performing comparability non-clinical and/or clinical studies between the product manufactures by its existing manufacturer and the product manufactured at our manufacturing facility. There is no assurance that we will be able to provide supporting comparability results that meet all regulatory requirements needed to obtain the regulatory approval required to be able to commence commercial manufacturing of new plasma-derived products in our manufacturing plant.

If we are unable to adequately complete the required development and/or technology transfer projects or subsequently obtain the required regulatory approvals, we will not be able to utilize the excess capacity of our manufacturing plant and may suffer reduced profitability or operating losses.

We may not realize the anticipated benefits of our recent agreement for the acquisition of the plasma collection operations of B&PR, the purpose of which is to become less dependent on plasma supply from third parties and reduce costs associated with source plasma procurement.

As recently announced, in January 2021 we entered into an agreement for the acquisition, subject to customary closing conditions, of the plasma collection center of B&PR in Beaumont, Texas, which specializes in the collection of hyper-immune plasma used in the manufacture of Anti-D immunoglobulin products ("Anti-D products"). B&PR's plasma collection center is one of the few FDA-licensed centers in the U.S. producing the raw materials required for these products. The acquisition of B&PR's plasma collection center shall represent our entry into the U.S. plasma collection market and further our strategic goal of becoming a fully integrated specialty plasma company. We plan to significantly expand our hyperimmune plasma collection capacity by investing in B&PR's plasma collection center at Beaumont, Texas and leveraging its FDA license to open additional centers in the U.S. However, given our limited prior experience in managing plasma collection operations as well as the operational, technical and regulatory challenges in maintaining plasma collection operations, we may not be able to realize the anticipated benefits of the acquisition. We may not be able to adequately collect all sufficient quantities of plasma through our plasma collection operations and there can be no assurance that we will be able to reduce the cost of plasma through our collection operations, as compared to costs associated with acquisition of plasma from third parties.

See also "*—We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements or if prices of the source plasma or plasma derivatives were to raise significantly"*; and *"—We may engage in strategic transactions to acquire assets, businesses, or rights to products, product candidates or technologies or form collaborations or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense."*

Our two leading product development candidates are Inhaled AAT for AATD and Anti-SARS-CoV-2 IgG as a potential therapy for COVID-19; and in addition, we have several other early stage development projects. There can be no assurance that the development activities associated with these products will materialize and result in the FDA, EMA or any other relevant agencies granting us marketing authorization for any of these products.

Our two leading product development candidates are Inhaled AAT for AATD and Anti-SARS-CoV-2 IgG as a potential therapy for COVID-19; and in addition, we have several other early stage development projects.

During December 2019, the first patient was randomized in Europe into our pivotal Phase 3 InnovAATe clinical trial evaluating the safety and efficacy of our proprietary inhaled AAT therapy for the treatment of AATD. The study was initiated following extensive discussions with both the FDA and EMA regarding the trial's design as well a thorough analysis of a prior pivotal Phase 2/3 clinical trial for Inhaled AAT for AATD conducted in Europe, which did not meet its primary or other pre-defined efficacy endpoints. In addition to the pivotal study and based on feedback received from the FDA regarding anti-drug antibodies ("ADA") to Inhaled AAT, we intend to concurrently conduct a sub-study in North America in which approximately 30 patients will be evaluated for the effect of ADA on AAT levels in plasma with Inhaled AAT and IV AAT treatments. There can be no assurance that we will be able to complete this study successfully or that the study results will be sufficient for obtaining FDA and EMA approval. See also "*As a result of the COVID-19 pandemic we have encountered delays in patient recruitment into our pivotal Phase 3 InnovAAT clinical study conducted at a first study site in Europe and it has impacted and may continue to impact our ability to open additional study sites in the United States and Europe."*

In response to the recent COVID-19 outbreak, in early 2020 we initiated the development of our Anti-SARS-CoV-2 IgG product as a potential treatment for COVID-19. In August 2020, we initiated a Phase 1/2 open-label, single-arm, multi-center clinical trial in Israel of our product; and in September 2020, we announced initial interim results for the Phase 1/2 clinical trial. We subsequently submitted a pre-Investigational New Drug ("IND") information package to the FDA with our proposed U.S. clinical development plan. Following recent response from the FDA to our information package, we continue to evaluate the best suitable plan for the U.S. and/or EU Anti-SARS-CoV-2 IgG clinical program, and will advance the development of the product upon the conclusion of this review. There can be no assurance that we will be able to successfully complete the additional requirement for submission of an IND and thereafter initiate a clinical development program required as a basis for a potential approval of the product.

In addition, we are currently engaged in the development of other product candidates, including a recombinant AAT product candidate as well as testing our intravenous AAT product for other indications such as organ preservation, and there can be no assurance that such development activities will progress and obtain the required regulatory approvals.

See also: "*Research and development efforts invested in our pipeline of specialty and other products may not achieve expected results"* and "*—If we are unable to successfully introduce new products and indications or fail to keep pace with advances in technology, our business, financial condition and results of operations may be adversely affected*."

We may engage in strategic transactions to acquire assets, businesses, or rights to products, product candidates or technologies or form collaborations or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense.

As part of our business development strategy, we may engage in strategic transactions to expand and diversify our product portfolio, including through the acquisition of assets, businesses, or rights to products, product candidates or technologies or through strategic alliances or collaborations, such as the recent B&PR transaction. We may not identify suitable strategic transactions, or complete such transactions in a timely manner, on a cost-effective basis, or at all. Moreover, we may devote resources to potential opportunities that are never completed, or we may incorrectly judge the value or worth of such opportunities. Even if we successfully execute a strategic transaction, we may not be able to realize the anticipated benefits of such transaction, may incur additional debt or assume unknown or contingent liabilities in connection therewith, and may experience losses related to our investments in such transactions. Integration of an acquired company or assets into our existing business may not be successful and may disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, and require management resources that would otherwise focus on developing our existing business. Even if we are able to achieve the long-term benefits of a strategic transaction, our expenses and short-term costs may increase materially and adversely affect our liquidity. Any of the foregoing could have a material effect on our business, results of operations and financial condition.

In addition, strategic transactions, such as the recent B&PR transaction, may entail numerous operational, financial and legal risks, including:

- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- exposure to known and unknown liabilities, including possible intellectual property infringement claims, violations of laws, tax liabilities and commercial disputes;
- higher than expected acquisition and integration costs;
- difficulty in integrating operations and personnel of any acquired business;
- increased amortization expenses or, in the event that we write-down the value of acquired assets, impairment losses;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain personnel, customers, distributors, vendors and other business partners integral to an in-licensed or acquired product, product candidate or technology;
- potential failure of the due diligence processes to identify significant problems, liabilities or other shortcomings or challenges;

- entry into indications or markets in which we have no or limited direct prior development or commercial experience and where competitors in such markets have stronger market positions; and

- other challenges associated with managing an increasingly diversified business.

If we are unable to successfully manage any strategic transaction in which we may engage, our ability to develop new products and continue to expand and diversify our product pipeline, increase our sales and profitability may be limited.

The COVID-19 pandemic may adversely impact our business, operating results and financial condition.

The novel coronavirus identified in late 2019, SARS-CoV-2, which causes the disease known as COVID-19, is an ongoing global pandemic that has resulted in public and governmental efforts to contain or slow the spread of the disease, including widespread shelter-in-place orders, social distancing interventions, quarantines, travel restrictions and various forms of operational shutdowns. The COVID-19 pandemic and the resulting measures implemented in response to the pandemic are adversely affecting, and is expected to continue to adversely affect, a number of our business activities (including our research and development, clinical trials, operations, supply chains, distribution systems, product development and sales activities) as well as those of our suppliers, customers, third-party payers and patients. Due to the impact of the pandemic and these measures, we have experienced, and expect to continue to experience, unpredictable reductions in demand for certain of our products, and in some cases, have experienced, and could continue to experience, unpredictable increases in demand for certain of our products. The outbreak and preventative or protective actions that governments, corporations, individuals or we have taken or may take in the future to contain the spread of COVID-19 may result in a period of reduced operations, reduced product demand or limit the ability of customers to perform their obligations to us, delays in clinical trials or other research and development efforts, business disruption for us and our suppliers, customers and other third parties with which we do business and potential delays or disruptions related to regulatory approvals.

While COVID-19 related disruption had various effects on our business activities, commercial operation, revenues and operational expenses, as a result of the actions we have taken to date, our overall results of operations for the year ended December 31, 2020 were not materially affected. However, a number of factors, including but not limited to, continued effect of the factors mentioned above as well as, continued demand for our products, including GLASSIA and KEDRAB in the U.S. market and our distributed products in Israel, financial conditions of our customers, distributors, suppliers and services providers, our ability to manage operating expenses, additional competition in the markets that we compete, delays in clinical trials or other research and development efforts, regulatory delays, professional and operational costs increase (including insurance costs), prevailing market conditions and the impact of general economic, industry or political conditions in the U.S., Israel or otherwise, may have an effect on our future financial position and results of operations.

The financial impact of these factors cannot be reasonably estimated at this time but may materially affect our business, financial condition and results of operations, and the trading prices of our ordinary shares were impacted by volatility in the financial markets resulting from the pandemic. The full extent to which the pandemic impacts our business, results or the trading price of our ordinary shares will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and duration of the pandemic and actions to contain its spread or treat its impact, among others.

The COVID-19 pandemic and the volatile global economic conditions stemming from it may precipitate or amplify the other risks described in this "Risk Factors" section of this Annual Report, which could materially adversely affect our business, operations and financial conditions and results from operations.

Risks Related to Our Proprietary Products Segment

In our Proprietary Products segment, we rely on Kedrion for the sales of our KEDRAB product in the United States and the development and expected sales of our investigational Anti-SARS-CoV-2 IgG product as a potential treatment for COVID-19 in the United States, Europe and additional countries, and any disruption to our relationships with Kedrion would have an adverse effect on our future results of operations and profitability.

Pursuant to the strategic distribution and supply agreement with Kedrion for the clinical development and marketing in the United States of KEDRAB, Kedrion is the sole distributor of KEDRAB in the United States. Sales to Kedrion accounted for approximately 14%, 13% and 10% of our total revenues in the years ended December 31, 2020, 2019 and 2018, respectively. We are dependent on Kedrion for its marketing and sales of KEDRAB in the United States.

We also primarily depend upon KedPlasma, a subsidiary of Kedrion, for the supply of the hyper-immune plasma which is used for the production of KEDRAB to be sold in the United States and of KAMRAB to be sold in other markets. See "*—We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements or if prices of the source plasma or plasma derivatives were to raise significantly*."

In addition, pursuant to the global collaboration engagement that we entered into with Kedrion for the development, manufacturing and distribution of our investigational Anti-SARS-CoV-2 IgG product as a potential treatment for COVID-19, we are dependent on Kedrion for the supply of plasma, collected at its KedPlasma centers, from donors who have recovered from the virus, which shall be used as starting material for such product and, upon future receipt, based on the development plan, of regulatory approvals, Kedrion shall be the sole distributor of the product in the U.S., Europe, Australia, South Korea, United Kingdom, Switzerland and Norway.

If we fail to maintain our relationship with Kedrion, we could face significant costs in finding a replacement distributor for the sales of KEDRAB in the United States and a replacement supplier of the hyper-immune plasma which is used for the production of KEDRAB, as well as a replacement supplier of plasma for the development and manufacturing of our Anti-SARS-CoV-2 IgG product. Delays in establishing a relationship with a new distributor and supplier could lead to a decrease in our KEDRAB sales and a deterioration in our market share when compared with one or more of our competitors, or delays in the development, manufacturing and sales of our investigational Anti-SARS-CoV-2 IgG product. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

In our Proprietary Products segment, we currently rely on Takeda for sales of GLASSIA in the U.S. market, and any reduction in sales of GLASSIA by Takeda would have an adverse effect on our future expected royalty income, results of operations and profitability.

Based on our manufacturing, supply and distribution agreement with Takeda, following the transition of manufacturing to Takeda, upon initiation of sales of GLASSIA manufactured by Takeda, Takeda will pay royalties to us at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040. Based on current GLASSIA sales in the United States and forecasted future growth, we project receiving royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040. However, any reduction in sales of GLASSIA by Takeda or should Takeda reduce its manufacturing and marketing of GLASSIA for any reason (including but not limited to inability to adequately or sufficiently manufacture GLASSIA, regulatory limitations, difficulties in marketing, reduction in market size, or changes in corporate focus), our future expected royalty income from Takeda's sales of GLASSIA would be adversely impacted, which would have an adverse effect on our results of operations and profitability.

Certain of our sales in our Proprietary Products segment rely on our ability to win tender bids based on the price and availability of our products in public tender processes.

Certain of our sales in our Proprietary Products segment rely on our ability to win tender bids in certain markets, including those of the World Health Organization (WHO) and other similar health organizations. Our ability to win bids may be materially adversely affected by competitive conditions in such bid process. Our existing and new competitors may also have significantly greater financial resources than us, which they could use to promote their products and business. Greater financial resources would also enable our competitors to substantially reduce the price of their products or services. If our competitors are able to offer prices lower than us, our ability to win tender bids during the tender process will be materially affected and could reduce our total revenues or decrease our profit margins.

In our Proprietary Products segment, we rely on third party distributors for the distribution and sales of our products in ex-U.S. markets (other than the Israeli market), and any disruption to our relationships with these third party distributers would have an adverse effect on our future results of operations and profitability.

We engage third party distributors in ex-U.S. markets to distribute and sell our Proprietary Products. Sales through distributors in ex-U.S. markets (other than the Israeli market) accounted for approximately 10%, 8% and 10% of our total revenues in the years ended December 31, 2020, 2019 and 2018, respectively. We are dependent of these third parties for marketing, distribution and sales of our products in these markets.

In addition to distribution and sales, these third party distributors are, in most cases, responsible for the regulatory registration of our products in the local markets in which they operate, as well as responsible for participation in tenders for sale of our products. Failure of the third party distributors to obtain and maintain such regulatory approvals and/or win tenders or provide competitive prices to our products may adversely affect our ability to sell our Proprietary Products in these markets, which in turn will negatively affect our revenues and profitability. In addition, our inability to sell our Proprietary Products in these markets may reduce our manufacturing plant utilization and effectiveness, and may lead to additional reduction of profitability.

Our Proprietary Products segment operates in a highly competitive market.

We compete with well-established drug companies, including two to four large competitors for each of our products in the Proprietary Products segment. These large competitors include CSL Behring Ltd. ("CSL"), Takeda, and Grifols S.A. ("Grifols"), which acquired a competitor, Talecris Biotherapeutics, Inc. ("Talecris") in 2011, and Kedrion. We compete against these companies for, among other things, licenses, expertise, clinical trial patients and investigators, consultants and third-party strategic partners. We also compete with these companies for market share for certain products in the Proprietary Products segment. Our large competitors have advantages in the market because of their size, financial resources, markets and the duration of their activities and experience in the relevant market, especially in the United States and countries of the European Union. As a result, they may be able to devote more funds to research and development and new production technologies, as well as to the promotion of their products and business. These competitors may also be able to sustain for longer periods a deliberate substantial reduction in the price of their products or services. These competitors also have an additional advantage regarding the availability of raw materials, as they own companies that collect plasma and/or plants which fractionate plasma.

Our products generally do not benefit from patent protection and compete against similar products produced by other providers. Additionally, the development by a competitor of a similar or superior product or increased pricing competition may result in a reduction in our net sales or a decrease in our profit margins. For example, we believe that our two main competitors in the AAT market are Grifols and CSL. We estimate that Grifols' AAT by infusion product for the treatment of AATD, Prolastin A1PI, accounts for at least 50% market share in the United States and more than 70% of sales in the worldwide market for the treatment of AATD, which also includes sales of Prolastin in different European countries. Apart from its sales through Talecris' historical business, Grifols is also a local producer of the product in the Spanish market and operates in Brazil. CSL's intravenous AAT product is mainly sold in the United States. In 2015, CSL's intravenous AAT product was granted centralized marketing authorization in Europe and CSL has launched the product in a few European countries since 2016. There is another, smaller local producer in the French market, LFB S.A. In addition, we estimate that each of Grifols and CSL owns approximately 200-250 operating plasma collection centers located across the United States.

Similarly, if a new AAT formulation or a new route of administration with significantly improved characteristics is adopted (including, for example, aerosol inhalation), the market share of our current AAT product, GLASSIA, could be negatively impacted. While we are in the process of developing Inhaled AAT for AATD, our competitors may also be attempting to develop similar products. For example, several of our competitors may have completed early stage clinical trials for the development of an inhaled formulation of AAT for different indications. While these products are in the early stages of development, they may eventually be successfully developed and launched. Furthermore, even if we are able to commercialize Inhaled AAT for AATD prior to the development of comparable products by our competitors, sales of Inhaled AAT for AATD, subject to approval of such product by the applicable regulatory authorities, could adversely impact our revenue and growth of sales of GLASSIA or GLASSIA -related royalties.

In addition, our plasma-derived protein therapeutics face, or may face in the future, competition from existing or newly developed non-plasma products and other courses of treatments. New treatments, such as gene therapy, small molecules, correctors, monoclonal or recombinant products, may also be developed for indications for which our products are now used. Our competitors are attempting to develop similar products or products that could be a substitute for AAT product. For example, several of our competitors are conducting preclinical and clinical trials for the development of gene therapy or correctors for AATD. While these products are in the early stages of development, they may eventually be successfully developed and launched, and could adversely impact our revenue and growth of sales of GLASSIA or GLASSIA -related royalties as well as affect our ability to launch our Inhaled AAT product, if approved.

We believe that there are two main competitors for KamRAB/KEDRAB, our anti-rabies products, worldwide: Grifols, whose product we estimate comprises approximately 70%-80% of the anti-rabies market in the United States, and CSL, which sells its anti-rabies product in Europe and elsewhere. In addition, Sanofi Pasteur, the vaccines division of Sanofi S.A., has a product registered for the United States market, but the product is primarily sold in Europe and not currently sold in significant quantities in the United States. There are a number of local producers in other countries that make similar anti-rabies products, most of which are based on equine serum. Over the past several years, several companies have made attempts, and some are still in the process of developing monoclonal antibodies for an anti-rabies treatment. These products, if approved, may be as effective as the currently available plasma derived anti-rabies vaccine and may potentially be significantly cheaper, and as such may result in loss of market share of KamRAB/KEDRAB.

While Kedrion is our strategic partner for KEDRAB, it is also one of our competitors for KamRho(D). In addition to its sales in the United States, Kedrion also markets a competing product in several EU countries as well as other countries world-wide. We believe there are three additional main suppliers of competitive products in this market: Grifols, CSL and Saol Therapeutics. There are also local producers in other countries that make similar products mostly intended for local markets.

In the wake of the COVID-19 pandemic we, together with our partner Kedrion, initiated the development of our investigational Anti-SARS-CoV-2 IgG product as a potential therapy for COVID-19. In parallel, the CoVIg-19 Plasma Alliance partnership was formed of the world's leading plasma companies, spanning plasma collection, development, production, and distribution with the goal to accelerate the development of a potential treatment and increase supply of the potential treatment. In addition to Biotest, BPL, CSL Behring, LFB, Octapharma, and Takeda which formed the Alliance, the following additional industry members are reported to have joined the Alliance: ADMA Biologics, BioPharma Plasma, GC Pharma, Liminal BioSciences, and Sanquin. The Alliance is developing a plasma derived hyperimmune therapy for COVID-19 which is based on plasma collected from convalescent COVID-19 patients, which is similar to our investigational product. In addition, the Alliance announced the initiation of the Inpatient Treatment with Anti-Coronavirus Immunoglobulin (the "ITAC") Phase 3 clinical trial sponsored by the National Institute of Allergy and Infectious Diseases ("NIAID"), part of the National Institutes of Health (the "NIH"), which will evaluate the safety, tolerability and efficacy of an investigational anti-coronavirus hyperimmune intravenous immunoglobulin (H-Ig) medicine for treating hospitalized adults at risk for serious complications of COVID-19 disease. If successful, the Alliance's product may become one of the treatment options for hospitalized COVID-19 patients. This product, if approved, may affect our ability to launch and/or market our Anti-SARS-CoV-2 investigational IgG product, if approved.

In addition, a number of companies are in the process of advanced development of monoclonal antibodies for an Anti-SARS-CoV-2 treatment, such as Regeneron's casirivimab and imdevimab which form a novel monoclonal antibody cocktail being studied for its potential both to treat appropriate patients with COVID-19 and to prevent SARS-CoV-2 infection, and Eli Lilly's investigational neutralizing antibody bamlanivimab (LY-CoV555) 700 mg. Bamlanivimab which received emergency use authorization from the FDA for the treatment of mild to moderate COVID-19 in adults and pediatric patients 12 years and older with a positive COVID-19 test, who are at high risk for progressing to severe COVID-19 and/or hospitalization. Moreover, the FDA issued an Emergency Use Authorization for convalescent plasma as a potential treatment for COVID–19. Convalescent plasma has played an important role in the immediate and intermediate response to the disease. These products, and similar others may be as effective as our plasma derived IgG product, may obtain approval from the FDA, EMA or other regulatory agencies sooner than our product and may potentially be significantly cheaper, and as such may affect our ability to launch and/or gain sufficient market share with our Anti-SARS-CoV-2 investigational IgG product, if approved.

Our products involve biological intermediates that are susceptible to contamination and the handling of such intermediates and our final products throughout the supply chain and manufacturing process requires clod-chain handling, all of which could adversely affect our operating results.

Plasma and its derivatives, such as fraction IV, are raw materials that are susceptible to damage and contamination and may contain microorganisms that cause diseases in humans, commonly known as human pathogens, any of which would render such materials unsuitable as raw material for further manufacturing. Almost immediately after collection from a donor, plasma and plasma derivatives must be stored and transported at temperatures that are at least -20 degrees Celsius (-4 degrees Fahrenheit). Improper storage or transportation of plasma or plasma derivatives by us or third-party suppliers may require us to destroy some of our raw material. In addition, plasma and plasma derivatives are also suitable for use only for certain periods of time once removed from storage. If unsuitable plasma or plasma derivatives are not identified and discarded prior to release to our manufacturing processes, it may be necessary to discard intermediate or finished products made from such plasma or plasma derivatives, or to recall any finished product released to the market, resulting in a charge to cost of goods sold and harm to our brand and reputation. Furthermore, if we distribute plasma-derived protein therapeutics that are produced from unsuitable plasma because we have not detected contaminants or impurities, we could be subject to product liability claims and our reputation would be adversely affected.

Despite overlapping safeguards, including the screening of donors and other steps to remove or inactivate viruses and other infectious disease-causing agents, the risk of transmissible disease through plasma-derived protein therapeutics cannot be entirely eliminated. If a new infectious disease was to emerge in the human population, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to manufacture our products. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for plasma-derived protein therapeutics. In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected plasma. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the plasma or plasma derivatives used in the production of our plasma-derived protein therapeutics. Additionally, this could trigger the need for changes in our existing inactivation and production methods, including the administration of new detection tests, which could result in delays in production until the new methods are in place, as well as increased costs that may not be readily passed on to our customers.

Plasma and plasma derivatives can also become contaminated through the manufacturing process itself, such as through our failure to identify and purify contaminants through our manufacturing process or failure to maintain a high level of sterility within our manufacturing facilities.

Once we have manufactured our plasma-derived protein therapeutics, they must be handled carefully and kept at appropriate temperatures. Our failure, or the failure of third parties that supply, ship, store or distribute our products, to properly care for our plasma-derived products, may result in the requirement that such products be destroyed.

While we expect small amounts of work-in-process inventories scraps in the ordinary course of business because of the complex nature of plasma and plasma derivatives, our processes and our plasma-derived protein therapeutics, unanticipated events may lead to write-offs and other costs materially in excess of our expectations. We have, in the past, experienced situations that have caused us to write-off the value of our products. Such write-offs and other costs could materially adversely affect our operating results. Furthermore, contamination of our plasma-derived protein therapeutics could cause consumers or other third parties with whom we conduct business to lose confidence in the reliability of our manufacturing procedures, which could materially adversely affect our sales and operating results.

Our ability to continue manufacturing and distributing our plasma-derived protein therapeutics depends on our continued adherence to current Good Manufacturing Practice regulations.

The manufacturing processes for our products are governed by detailed written procedures and regulations that set forth current Good Manufacturing Practice standards ("cGMP") requirements for blood products, including plasma and plasma derivative products. Failure to adhere to established procedures or regulations, or to meet a specification set forth in cGMP requirements, could require that a product or material be rejected and destroyed. There are relatively few opportunities for us to rework, reprocess or salvage nonconforming materials or products. Any failure in cGMP inspection will affect marketing in other territories, including the U.S. and Israel.

Our adherence to cGMP regulations and the effectiveness of our quality control systems are periodically assessed through inspections of our manufacturing facility in Beit Kama, Israel by the FDA, the IMOH and regulatory authorities of other countries. Such inspections could result in deficiency citations, which would require us to take action to correct those deficiencies to the satisfaction of the applicable regulatory authorities. If serious deficiencies are noted or if we are unable to prevent recurrences, we may have to recall products or suspend operations until appropriate measures can be implemented. The FDA could also stop the import of products into the United States if there are potential deficiencies. Such deficiencies may also affect our ability to obtain government contracts in the future. We are required to report certain deviations from procedures to the FDA. Even if we determine that the deviations were not material, the FDA could require us to take certain measures to address the deviations. Since cGMP reflects ever-evolving standards, we regularly need to update our manufacturing processes and procedures to comply with cGMP. These changes may cause us to incur additional costs and may adversely impact our profitability. For example, more sensitive testing assays (if and when they become available) may be required or existing procedures or processes may require revalidation, all of which may be costly and time-consuming and could delay or prevent the manufacturing of a product or launch of a new product.

We may face manufacturing stoppages and other challenges associated with audits or inspections by regulatory bodies.

The regulatory authorities may, at any time and from time to time, following approval of a product for sale, audit the facilities in which the product is manufactured. If any such inspection or audit of our facilities identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independently of such an inspection or audit, the relevant regulatory authority may require remedial measures that may be costly or time consuming for us to implement and that may include the temporary or permanent suspension of commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us with whom we contract could materially harm our business.

The biologic properties of plasma and plasma derivatives are variable, which may impact our ability to consistently manufacture our products in accordance with the approved specifications.

While our manufacturing processes were developed to meet certain product specifications, variations in the biologic properties of the plasma or plasma derivatives as well as the manufacturing processes themselves may result in out of specification results during the manufacturing of our products. While we expect certain work-in-process inventories scraps in the ordinary course of business because of the complex nature of plasma and plasma derivatives, our processes and our plasma-derived protein therapeutics, unanticipated events may lead to write-offs and other costs materially in excess of our expectations. We have, in the past, experienced situations that have caused us to write-off the value of our products. Such write-offs and other costs could materially adversely affect our operating results.

The biologic properties of plasma and plasma derivatives are variable, which may adversely impact our levels of product yield from our plasma or plasma derivative supply.

Due to the nature of plasma, there will be variations in the biologic properties of the plasma or plasma derivatives we purchase that may result in fluctuations in the obtainable yield of desired fractions, even if cGMP is followed. Lower yields may limit production of our plasma-derived protein therapeutics because of capacity constraints. If these batches of plasma with lower yields impact production for extended periods, we may not be able to fulfill orders on a timely basis and the total capacity of product that we are able to market could decline and our cost of goods sold could increase, thus reducing our profitability.

Usage of our products may lead to serious and unexpected side effects, which could materially adversely affect our business and may, among other factors, lead to our products being recalled and our reputation being harmed, resulting in an adverse effect on our operating results.

The use of our plasma-derived protein therapeutics may produce undesirable side effects or adverse reactions or events. For the most part, these side effects are known, are expected to occur at some frequency and are described in the products' labeling. Known side effects of a number of our plasma-derived protein therapeutics include headache, nausea and additional common protein infusion related events, such as flu-like symptoms, dizziness and hypertension. The occurrence of known side effects on a large scale could adversely affect our reputation and public image, and hence also our operating results.

In addition, the use of our plasma-derived protein therapeutics may be associated with serious and unexpected side effects, or with less serious reactions at a greater than expected frequency. This may be especially true when our products are used in critically ill patient populations. When these unexpected events are reported to us, we typically make a thorough investigation to determine causality and implications for product safety. These events must also be specifically reported to the applicable regulatory authorities, and in some cases, also to the public by media channels. If our evaluation concludes, or regulatory authorities perceive, that there is an unreasonable risk associated with one of our products, we would be obligated to withdraw the impacted lot or lots of that product or, in certain cases, to withdraw the product entirely. Furthermore, it is possible that an unexpected side effect caused by a product could be recognized only after extensive use of the product, which could expose us to product liability risks, enforcement action by regulatory authorities and damage to our reputation.

We are subject to a number of existing laws and regulations in multiple jurisdictions, non-compliance with which could adversely affect our business, financial condition and results of operations, and we are susceptible to a changing regulatory environment, which could increase our compliance costs or reduce profit margins.

Any new product must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by the FDA and similar authorities in other jurisdictions, including the EMA and the regulatory authorities in Israel. Our facilities must be approved and licensed prior to production and remain subject to inspection from time to time thereafter. Failure to comply with the requirements of the FDA or similar authorities in other jurisdictions, including a failed inspection or a failure in our reporting system for adverse effects of our products experienced by the users of our products, or any other non-compliance, could result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, import or export restrictions, refusal or delay of a regulatory authority to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Furthermore, we may experience delays or additional costs in obtaining new approvals or licenses, or extensions of existing approvals and licenses, from a regulatory authority due to reasons that are beyond our control such as changes in regulations or a shutdown of the U.S. federal government, including the FDA, or similar governing bodies or authorities in other jurisdictions. In addition, we rely on Takeda, Kedrion and additional plasma suppliers, for plasma collection required for the manufacturing of GLASSIA, KEDRAB and other Proprietary products, and in the case of Takeda and Kedrion for the distribution of these products in the United States (and in the case of Takeda, also potentially in Canada, Australia and New Zealand). In performing such services to us, Takeda, Kedrion and additional plasma suppliers are required to comply with certain regulatory requirements. Any failure by Takeda and/or Kedrion and/or additional plasma suppliers to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements, could adversely affect us. Any of these actions could cause direct liabilities, a loss in our ability to market GLASSIA and/or KEDRAB and/or other Proprietary products, or a loss of customer confidence in us or in GLASSIA and/or KEDRAB and/or other Proprietary products, which could materially adversely affect our sales, future revenues, reputation, and results of operations. Similarly, we rely on other third-party vendors, for example, in the testing, handling, and distributions of our products. If any of these companies incur enforcement action from regulatory authorities due to noncompliance, this could negatively affect product sales, our reputation and results of operations. In addition, we rely on other distributors of our other proprietary products, for purposes of our distribution related regulatory compliance for the products they distribute in the territories in which they operate. Any failure by such distributors to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements, could adversely affect our sales, future revenues, reputation and results of operations.

Any changes in our production processes for our products must be approved by the FDA and/or similar authorities in other jurisdictions. Failure to comply with any requirements as to production process changes dictated by the FDA or similar authorities in other jurisdictions could also result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal or delay of a regulatory authority to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses.

In addition, changes in the regulation of our activities, such as increased regulation affecting safety requirements or new regulations such as limitations on the prices charged to customers in the United States, Israel or other jurisdictions in which we operate, could materially adversely affect our business. In addition, the requirements of different jurisdictions in which we operate may become less uniform, creating a greater administrative burden and generating additional compliance costs, which would have a material adverse effect on our profit margins.

We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements or if prices of the source plasma or plasma derivatives were to raise significantly.

Our proprietary products depend on our access to U.S., European or other territories' hyper-immune plasma or plasma derivatives, such as fraction IV. We purchase these plasma products from third-party licensed suppliers, including Takeda and Kedrion, some of which are also responsible for the plasma fractionation process, pursuant to multiple purchase agreements. We have entered into a number of plasma supply agreements with various third parties in the United States and Europe and with the IMOH in Israel (for the supply of plasma from convalescents COVID-19 patients required for our Anti-SARS-CoV-2 IgG product as a potential treatment for COVID-19) some of which are also strategic partners in the distribution of our proprietary products. These agreements contain various termination provisions, including upon a material breach of either party, force majeure and, with respect to supply agreements with strategic partners, the failure or delay on the part of either party to obtain the applicable regulatory approvals or the termination of the principal strategic relationship. If we are unable to obtain adequate quantities of source plasma or fraction IV plasma approved by the FDA, the EMA or the regulatory authorities in Israel from these providers, we may be unable to find an alternative cost-effective source.

In order for plasma and fraction IV plasma to be used in the manufacturing of our plasma-derived protein therapeutics, the individual centers at which the plasma is collected must be licensed and approved by the relevant regulatory authorities, such as the FDA, the EMA or the IMOH (for Anti SARS CoV2). When a new plasma collection center is opened, and on an ongoing basis after its licensure, it must be inspected by the FDA, the EMA or the regulatory authorities in Israel for compliance with cGMP and other regulatory requirements. An unsatisfactory inspection could prevent a new center from being licensed or lead to the suspension or revocation of an existing license. If relevant regulatory authorities determine that a plasma collection center did not comply with cGMP in collecting plasma, we may be unable to use and may ultimately destroy plasma collected from that center, which may impact on our ability to timely meet our manufacturing and supply obligations. Additionally, if noncompliance in the plasma collection process is identified after the impacted plasma has been pooled with compliant plasma from other sources, entire plasma pools, in-process intermediate materials and final products could be impacted, such as through product destruction or rework. Consequently, we could experience significant inventory impairment provisions and write-offs, which could adversely affect our business and financial results.

In addition, the plasma supplier's fractionation process must also meet standards of the FDA, the EMA or the regulatory authorities in Israel. If a plasma supplier is unable to meet such standards, we will not be able to use the plasma derivatives provided by such supplier, which may impact on our ability to timely meet our manufacturing and supply obligations.

If we were unable to obtain adequate quantities of source plasma or plasma derivatives approved by the FDA, the EMA or the regulatory authorities in Israel, we would be limited in our ability to maintain or increase current manufacturing levels of our plasma derivative products, as well as in our ability to conduct the research required to maintain our product pipeline. As a result, we could experience a substantial decrease in total revenues or profit margins, a potential breach of distribution agreements, a loss of customers, a negative effect on our reputation as a reliable supplier of plasma derivative products or a substantial delay in our production and strategic growth plans.

The ability to increase plasma collections may be limited, our supply of plasma and plasma derivatives could be disrupted or the cost of plasma and plasma derivatives could increase substantially, as a result of numerous factors, including a reduction in the donor pool, increased regulatory requirements, decreased number of plasma supply sources due to consolidation and new indications for plasma-derived protein therapeutics, which could increase demand for plasma and plasma derivatives and lead to shortages.

Plasma collection process is dependent on donors arriving in plasma collection centers and agreeing to donate plasma. During major healthcare events, such as the recent COVID-19 pandemic, the number of donors attending plasma collection centers reduces, which may adversely affect the availability of plasma and its derivatives. A significant shortage in plasma supply may adversely affect our ability to continue manufacturing our products, may result in shortages in our products in the market, and may result in reduced sales and profitability.

We are also dependent on a number of suppliers who supply specialty ancillary products used in the production process, such as specific gels and filters. Each of these specialty ancillary products is provided by a single, exclusive supplier. If these suppliers were unable to provide us with these specialty ancillary products, if our relationships with these suppliers deteriorate, or these suppliers' operations are negatively affected by regulatory enforcement due to noncompliance, the manufacture and distribution of our products would be materially adversely affected, which would adversely affect our sales and results of operations. See "*—If we experience equipment difficulties or if the suppliers of our equipment or disposable goods fail to deliver key product components or supplies in a timely manner, our manufacturing ability would be impaired and our product sales could suffer."*

Some of our required specialty ancillary products and other materials used in the manufacturing process are commonly used in the healthcare industry world-wide. If the global demand for these products increases due to healthcare issues, epidemics or pandemics, such as the recent coronavirus (COVID-19) pandemic, our ability to secure adequate supply at reasonable cost of such products may be negatively affected, which would materially adversely affect our ability to manufacture and distribute our products, which would adversely affect our sales and results of operations.

In addition, regulatory requirements, including cGMP regulations, continually evolve. Failure of our plasma suppliers to adjust their operations to conform to new standards as established and interpreted by applicable regulatory authorities would create a compliance risk that could impair our ability to sustain normal operations.

In addition, if the purchase prices of the source plasma or plasma derivatives that we use to manufacture our proprietary products were to raise significantly, we may not be able to pass along these increased plasma and plasma-derivative prices to our customers. Prices in many of our principal markets are subject to local regulation and certain pharmaceutical products, such as plasma-derived protein therapeutics, are subject to price controls. Any inability to pass costs on to our customers due to these factors or others would reduce our profit margins. In addition, most of our competitors have the ability to collect their own source plasma or produce their own plasma derivatives, and therefore their products' prices would not be impacted by such a price raise, and as a result any pricing changes by us in order to pass higher costs on to our customers could render our products noncompetitive in certain territories.

We have been required to conduct post-approval clinical trials of GLASSIA and KEDRAB as a commitment to continuing marketing such products in the United States, and we may be required to conduct post-approval clinical trials as a condition to licensing or distributing other products.

When a new product is approved, the FDA or other regulatory authorities may require post-approval clinical trials, sometimes called Phase 4 clinical trials. For example, the FDA has required that we conduct Phase 4 clinical trials of GLASSIA, which began in 2015, and for KEDRAB, which began in 2017 and was completed in 2020 and its results were submitted for review by the FDA. Such Phase 4 clinical trials are aimed at collecting additional safety data, such as the immune response in the body of a human or animal, commonly referred to as immunogenicity, viral transmission, levels of the protein in the lung, or epithelial lining fluid, and certain efficacy endpoints requested by the FDA. If the results of such trials are unfavorable and demonstrate a previously undetected risk or provide new information that puts patients at risk, or if we fail to complete such trials as instructed by the FDA, this could result in receiving a warning letter from the FDA and the loss of the approval to market the product in the United States and other countries, or the imposition of restrictions, such as additional labeling, with a resulting loss of sales. Furthermore, there can be no assurance that the FDA will accept the results of any post-marketing commitment study, such as the results of the KEDRAB study, and under certain circumstances the FDA require a subsequent study. Other products we develop may face similar requirements, which would require additional resources and which may not be successful. We may also receive approval, which is conditional on successful additional data or clinical development, and failure in such further development may require similar changes to our product label or result in revocation of our marketing authorization.

The nature of producing and developing plasma-derived protein therapeutics may prevent us from responding in a timely manner to market forces and effectively managing our production capacity.

The production of plasma-derived protein therapeutics is a lengthy and complex process. Our ability to match our production of plasma-derived protein therapeutics to market demand is imprecise and may result in a failure to meet the market demand for our plasma-derived protein therapeutics or potentially in an oversupply of inventory. Failure to meet market demand for our plasma-derived protein therapeutics may result in customers transitioning to available competitive products, resulting in a loss of segment share or distributor or customer confidence. In the event of an oversupply in the market, we may be forced to lower the prices we charge for some of our plasma-derived protein therapeutics, record asset impairment charges or take other action which may adversely affect our business, financial condition and results of operations.

Risks Related to Our Distribution Segment

Our Distribution segment is dependent on a few suppliers, and any disruption to our relationship with these suppliers, or their inability to supply us with the products we sell, in a timely manner, in adequate quantities and/or at a reasonable cost, would have a material adverse effect on our business, financial condition and results of operations.

Sales of products supplied by Bio Products Laboratories Ltd. ("BPL") and Biotest A.G., which are sold in our Distribution segment, together represented approximately 22%, 19% and 17% of our total revenues for the years ended December 31, 2020, 2019 and 2018, respectively. While we have distribution agreements with each of our suppliers, these agreements do not obligate these suppliers to provide us with minimum amounts of our Distribution segment products. Purchases of our Distribution segment products from our suppliers are typically on a purchase order basis. We work closely with our suppliers to develop annual forecasts, but these forecasts are not obligations or commitments. However, if we fail to submit purchase orders that meet our annual forecasts or if we fail to meet our minimum purchase obligations, we could lose exclusivity or, in certain cases, the distribution agreement could be terminated.

These suppliers may experience capacity constraints that result in their being unable to supply us with products in a timely manner, in adequate quantities and/or at a reasonable cost. Contributing factors to supplier capacity constraints may include, among other things, industry or customer demands in excess of machine capacity, labor shortages, changes in raw material flows or shortages in raw materials which may result from different market conditions including, but not limited to, shortages resulting from increased global demand for these raw materials due to global healthcare issues, epidemics and pandemics, such as the coronavirus (COVID-19) pandemic. These suppliers may also choose not to supply us with products at their discretion or raise prices to a level that would render our products noncompetitive. Any significant interruption in the supply of these products could result in us being unable to meet the demands of our customers, which would have a material adverse effect on our business, financial condition and results of operations as a result of being required to pay of fines or penalties, be subject to claims of reach of contract, loss of reputation or even termination of agreement.

If our relationship with either distributor deteriorated, our distribution sales could be adversely affected. If we fail to maintain our existing relationships with these suppliers, we could face significant costs in finding a replacement supplier, and delays in establishing a relationship with a new supplier could lead to a decrease in our sales and a deterioration in our market share when compared with one or more of our competitors.

Additionally, our future growth in the Distribution segment is dependent on our ability to successfully engage other manufacturers for distribution in Israel of other products. Failure to engage new suppliers may have an adverse effect on our revenue growth and profitability.

Certain of our sales in our Distribution segment rely on our ability to win tender bids based on the price and availability of our products in annual public tender processes.

Certain of our sales in our Distribution segment rely on our ability to win tender bids during the annual tender process in Israel, as well as on sales made to health maintenance organizations (HMOs), hospitals and to the IMOH. Our ability to win bids may be materially adversely affected by competitive conditions in such bid process. Our existing and new competitors may also have significantly greater financial resources than us, which they could use to promote their products and business. Greater financial resources would also enable our competitors to substantially reduce the price of their products or services. If our competitors are able to offer prices lower than us, our ability to win tender bids during the annual tender process will be materially affected, and could reduce our total revenues or decrease our profit margins.

Certain of our products in both segments have historically been subject to price fluctuations as a result of changes in the production capacity available in the industry, the availability and pricing of plasma, development of competing products and the availability of alternative therapies. Higher prices for plasma-derived protein therapeutics have traditionally spurred increases in plasma production and collection capacity, resulting over time in increased product supply and lower prices. As demand continues to grow, if plasma supply and manufacturing capacity do not commensurately expand, prices tend to increase. Additionally, consolidation in plasma companies has led to a decrease in the number of plasma suppliers in the world, as either manufacturers of plasma-based pharmaceuticals purchase plasma suppliers or plasma suppliers are shut down in response to the number of manufacturers of plasma-based pharmaceuticals decreasing, which may lead to increased prices. We may not be able to pass along these increased plasma and plasma-derivative prices to our customers, which would reduce our profit margins.

Sales of our Distribution segment products are made through public tenders of Israeli hospitals and HMOs on an annual basis or in the private market based on detailing activity made by our medical representatives. The prices we can offer, as well as the availability of products, are key factors in the tender process. If our suppliers in the Distribution segment cannot sell us products at a competitive price or cannot guarantee sufficient quantities of products, we may lose the tenders.

Our Distribution segment is dependent on a few customers, and any disruption to our relationship with these customers, or our inability to supply, in a timely manner, in adequate quantities and/or at a reasonable cost, would have a material adverse effect on our business, financial condition and results of operations.

The Israeli market for drug products includes a relatively small number of HMOs and several hospitals. Sales to Clalit Health Services, an Israeli HMO, accounted for approximately 41%, 47% and 45% of our Distribution Segment revenues in the years ended December 31, 2020, 2019 and 2018, respectively.

If our relationship with any of our Israeli customers deteriorated, our distribution sales could be adversely affected. Failure to maintain our existing relationships with these customers could lead to a decrease in our revenues and profitability.

Before we may sell products in the Distribution segment, we must register the products with the IMOH and there can be no assurance that such registration will be obtained.

Before we may sell products in the Distribution segment in Israel, we must register the products, at our own expense, with the IMOH. We cannot predict how long the registration process of the IMOH may take or whether any such registration ultimately will be obtained. The IMOH has substantial discretion in the registration process and we can provide no assurance of success of registration. Our business, financial condition or results of operations could be materially adversely affected if we fail to receive IMOH registration for the products in the Distribution segment.

Our Distribution segment is a low-margin business and our profit margins may be sensitive to various factors, some of which are outside of our control.

Our Distribution segment is characterized by high volume sales with relatively low profit margins. Volatility in our pricing may have a direct impact on our profitability. Prolonged periods of product cost inflation may have a negative impact on our profit margins and results of operations to the extent we are unable to pass on all or a portion of such product cost increases to our customers. In addition, if our product mix changes, we may face increased risks of compression of our margins, as we may be unable to achieve the same level of profit margins as we are able to capture on our existing products. Our inability to effectively price our products or to reduce our expenses due to volatility in pricing could have a material adverse impact on our business, financial condition or results of operations.

We may be subject to milestone payments in connection with our Distribution segment products irrespective of whether the commercialization is successful.

Certain of our agreements in the Distribution segment, including agreements for distribution of biosimilar product candidates, require us to make milestone payments in advance of product launch. In some cases we may not be able to obtain reimbursement for such payments. To the extent that we are not ultimately able to recoup these payments, our business, financial position and results of operations may be adversely affected.

We may face competition in our Distribution segment.

In the Distribution segment, we face competition for our distribution products that are marketed in Israel and compete for market share. We believe that there are a number of companies active in the Israeli market distributing the products of several manufacturers whose comparable products compete with our products in the Distribution segment. In the plasma area, these manufacturers include Grifols, Takeda, CSL, Omrix Biopharmaceuticals Ltd. (a Johnson & Johnson company), while in other specialties we may be competing against products produced by some of the largest pharmaceutical manufacturers in the world, such as, Novartis AG, AstraZeneca AB, Sanofi UK and GlaxoSmithKline. Each of these competitors sells its products through a local subsidiary or a local representative in Israel. Our existing and new competitors may have significantly greater financial resources than us, which they could use to promote their products and business or reduce the price of their products or services. If we are unable to maintain or increase our market share, we may need to reduce prices and may suffer reduced profitability or operating losses, which could have a material adverse impact on our business, financial condition or results of operations.

We recently entered into agreements for future distribution in Israel of several biosimilar product candidates, and the successful future distribution of these products is dependent upon several factors some of which are beyond our control.

We recently entered into agreements with respect to planned distribution in Israel of certain biosimilar product candidates. Biosimilar products are highly similar to biological products already licensed for distribution by the FDA, EMA or any other relevant regulatory agency, notwithstanding minor differences in clinically inactive components, and that they have no clinically meaningful differences, as compared to the marketed biological products in terms of the safety, purity and potency of the products. The similar nature of a biosimilar and a reference product is demonstrated by comprehensive comparability studies covering quality, biological activity, safety and efficacy.

In order to launch biosimilar products in Israel we would need to obtain IMOH marketing authorization, which will be subject to prior authorization by the FDA or the EMA that should be obtained by the manufacturer of the biosimilar product candidate. Even if an FDA or EMA authorization is provided, there can be no assurance that the IMOH will accept such authorization as a reference and will grant us the authorization to distribute such biosimilar products in the Israeli market. In the event we will not be able to obtain the necessary marking authorization to launch the products, we may not generate the expected sale and profitability from these products which could have a material adverse impact on our business, financial condition or results of operations.

Innovative pharmaceutical products are generally protected for a defined period by various patents (including those covering drug substance, drug product, approved indications, methods of administration, methods of manufacturing, formulations and dosages) and/or regulatory exclusivity, which are intended to provide their holders with exclusive rights to market the products for the life of the patent or duration of the regulatory data protection period. Biosimilar products are intended to replace such innovative pharmaceutical upon the expiration or termination of their exclusivity period or in such markets whereby such exclusivity does not exist. The launch of a biosimilar product may potentially result in the infringement of certain IP rights and exclusivity and be subject to potential legal proceedings and restraining orders effecting its potential launch. Such intellectual property threats may preclude commercialization of such biosimilar product candidates, may result in incurring significant legal expenses and liabilities and we may not generate the expected sale and profitability from these products, which could have a material adverse impact on our business, financial condition or results of operations.

In addition, the commercialization of biosimilars includes the potential for steeper than anticipated price erosion due to increased competitive intensity, and lower uptake for biosimilars due to various factors that may vary for different biosimilars (e.g., anti-competitive practices, physician reluctance to prescribe biosimilars for existing patients taking the originator product, or misaligned financial incentives), all of which may affect our potential sales and profitability from these products which could have a material adverse impact on our business, financial condition or results of operations.

Risk Related to Development, Regulatory Approval and Commercialization of Product Candidates

Drug product development including preclinical and clinical trials is a lengthy and expensive process and may not result in receipt of regulatory approval.

Before obtaining regulatory approval for the sale of our product candidates, including Inhaled AAT for AATD and our Anti-SARS-CoV-2 IgG product, or for the marketing of existing products for new indications, we must conduct, at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We cannot predict how long the approval processes of the FDA, the EMA, the regulatory authorities in Israel or any other applicable regulatory authority or agency for any of our product candidates will take or whether any such approvals ultimately will be granted. The FDA, the EMA, the regulatory authorities in Israel and other regulatory agencies have substantial discretion in the relevant drug approval process over which they have authority, and positive results in preclinical testing or early phases of clinical studies offer no assurance of success in later phases of the approval process. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country.

Preclinical and clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. For example, the Phase 2/3 clinical trial in Europe for Inhaled AAT for AATD did not meet its primary or secondary endpoints and we subsequently withdrew the MAA in Europe for our Inhaled AAT for AATD.

While we have initiated the development of our investigational Anti-SARS-CoV-2 IgG product in the wake of the COVID-19 pandemic, due to the lengthy development and required regulatory process as well as the dependency on continued collection and supply of plasma from COVID-19 convalescent patients, we may not be able to supply our product prior to the potential wind-down of the pandemic.

As a result of the COVID-19 pandemic we have encountered delays in patient recruitment into our pivotal Phase 3 InnovAAT clinical study conducted at a first study site in Europe and it has impacted and may continue to impact our ability to open additional study sites in the United States and Europe.

During December 2019, we announced that the first patient was randomized in Europe into our pivotal Phase 3 InnovAATe clinical trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial designed to assess the efficacy and safety of Inhaled AAT in patients with AATD and moderate lung disease. Under the study design, up to 250 patients will be randomized 1:1 to receive either Inhaled AAT at a dose of 80mg once daily, or placebo, over two years of treatment. Enrolment into the trial continued through February 2020, however, thereafter was temporarily halted due to the impact of COVID-19 pandemic on healthcare systems. Although we recently resumed recruitment to the study, the COVID-19 pandemic has slowed down the rate of recruitment and the current pandemic situation mainly across Europe affects our ability to currently open new study sites. While we are exploring several alternative approaches to address the expected continuation of the pandemic and its effect on the study, there can be no assurance that we will be able to open additional site and significantly increase the rate of patient recruitment. This situation may cause a material delay in completing this study, or otherwise may require us to halt the study completely or reduce the overall size of the study which might not be acceptable by the FDA and/or EMA. These circumstances may affect our ability to complete the study successfully or may prevent us from having sufficient information to file for and obtain regulatory approval for this product by the FDA, EMA or any other relevant regulatory agency.

We may encounter unforeseen events that delay or prevent us from receiving regulatory approval for our product candidates.

We have experienced other unforeseen events that have delayed our ability to receive regulatory approval for certain of our product candidates, and may in the future experience similar or other unforeseen events during, or as a result of, preclinical testing or the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including that:

- delays may occur in obtaining our clinical materials;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or to abandon strategic projects;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower or more difficult than we anticipate (due to various reasons including challenges that may be imposed as a result of events outside our control, such as the recent COVID-19 pandemic which resulted in a significant slow-down in patient recruitment to our on-going Inhaled AAT Phase 3 study), or participants may withdraw from our clinical trials at higher rates than we anticipate;
- delays may occur in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval;
- our strategic partners may not achieve their clinical development goals and/or comply with their relevant regulatory requirements, which could affect our ability to conduct our clinical trials or obtain marketing authorization;
- we may be forced to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks or if any participant experiences an unexpected serious adverse event;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- regulators may not authorize us to commence or conduct a clinical trial within a country or at a prospective trial site, or according to the clinical trial outline we propose;
- undetected or concealed fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review of one or more of our marketing applications by regulatory agencies, and result in the recall of any approved product distributed pursuant to data determined to be fraudulent;

- the cost of our clinical and preclinical trials may be greater than we anticipate;

- an audit of preclinical tests or clinical studies by the FDA, the EMA, the regulatory authorities in Israel or other regulatory authorities may reveal noncompliance with applicable regulations, which could lead to disqualification of the results of such studies and the need to perform additional tests and studies; and

- our product candidates may not achieve the desired clinical benefits, or may cause undesirable side effects, or the product candidates may have other unexpected characteristics.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if safety concerns arise, we may:

- be delayed in obtaining regulatory or marketing approval for our product candidates;

- be unable to obtain regulatory and marketing approval;

- decide to halt the clinical trial or other testing;

- be required to conduct additional trials under a conditional approval;

- be unable to obtain reimbursement for our products in all or some countries;

- only obtain approval for indications that are not as broad as we initially intend;

- have the product removed from the market after obtaining marketing approval from the FDA, the EMA, the regulatory authorities in Israel or other regulatory authorities; and

- be delayed in, or prevented from, the receipt of clinical milestone payments from our strategic partners.

Our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis is subject to a number of factors, including the size of the patient population, the time of year during which the clinical trial is commenced, the hesitance of certain patients to leave their current standard of care for a new treatment, and the number of other ongoing clinical trials competing for patients in the same indication and eligibility criteria for the clinical trial. During 2020, we encountered challenges to recruit patients to our ongoing pivotal Phase 3 InnovAAT clinical study as a result of the COVID-19 pandemic, resulting in significant delays in recruitment. In addition, patients may drop out of our clinical trials at any point, which could impair the validity or statistical significance of the trials. Delays in patient enrollment or unexpected drop-out rates may result in longer development times.

Our product development costs will also increase if we experience delays in testing or approvals. There can be no assurance that any preclinical test or clinical trial will begin as planned, not need to be restructured or be completed on schedule, if at all. Because we generally apply for patent protection for our product candidates during the development stage, significant preclinical or clinical trial delays also could lead to a shorter patent protection period during which we may have the exclusive right to commercialize our product candidates, if approved, or could allow our competitors to bring products to market before we do, impairing our ability to commercialize our products or product candidates. For example, in the past, we have experienced delays in the commencement of clinical trials, such as a delay in patient enrollment (including as a result of the COVID-19 pandemic) for our clinical trials in Europe and the United States for Inhaled AAT for AATD.

Pre-clinical studies, including studies of our product candidates in animal models of disease, may not accurately predict the result of human clinical trials of those product candidates. In addition, product candidates studied in Phase 1 and 2 clinical trials may be found not to be safe and/or efficacious when studied further in Phase 3 trials. To satisfy FDA or other applicable regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 1 and 2 trials, does not ensure that later clinical trials will be successful. Initial results from Phase 1 and 2 clinical trials also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

We may not be able to commercialize our product candidates in development for numerous reasons.

Even if preclinical and clinical trials are successful, we still may be unable to commercialize a product because of difficulties in obtaining regulatory approval for its production process or problems in scaling that process to commercial production. In addition, the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge among jurisdictions and our third-party contractors, such as contract research organizations, may fail to comply with regulatory requirements or meet their contractual obligations to us.

Even if we are successful in our development and regulatory strategies, we cannot provide assurance that any product candidates we may seek to develop or are currently developing, such as Inhaled AAT for AATD and our Anti-SARS-CoV-2 IgG product, will ever be successfully commercialized. We may not be able to successfully address patient needs, persuade physicians and payors of the benefit of our product, and lead to usage and reimbursement. If such products are not eventually commercialized, the significant expense and lack of associated revenue could materially adversely affect our business.

We may not be able to successfully build and implement a commercial organization or commercialization program, with or without collaborating partners. The scale-up from research and development to commercialization requires significant time, resources, and expertise, which will rely, to a large extent, on third parties for assistance to help us in our efforts. Such assistance includes, but is not limited to, persuading physicians and payors of the benefit of our product to lead to utilization and reimbursement, developing a healthcare compliance program, and complying with post-marketing regulatory requirements.

We have initiated the development of a recombinant AAT product candidate, however, we may not be able to successfully complete its development or commercialize such product candidates for numerous reasons.

We have begun developing recombinant version of AAT, through external services of a Contract Development and Manufacturing Organization ("CDMO"), but we cannot be certain that such product will ever be approved or commercialized. See "Item 4. Information on the Company — Our Product Pipeline and Development Program — Recombinant AAT." The main advantage of recombinant AAT is its potentially wider availability, and ease of large-scale manufacturing. As a result, our product offerings may remain plasma-derived, even if our competitors offer competing recombinant or other non-plasma products or treatments.

If we are unable to successfully introduce new products and indications or fail to keep pace with advances in technology, our business, financial condition, and results of operations may be adversely affected.

Our continued growth depends, to a certain extent, on our ability to develop and obtain regulatory approvals of new products, new enhancements and/or new indications for our products and product candidates. Obtaining regulatory approval in any jurisdiction, including from the FDA, EMA or any other relevant regulatory agencies involves significant uncertainty and may be time consuming and require significant expenditures. See "—Research and development efforts invested in our pipeline of specialty and other products may not achieve expected results."

The development of innovative products and technologies that improve efficacy, safety, patients' and clinicians' ease of use and cost-effectiveness, involve significant technical and business risks. The success of new product offerings will depend on many factors, including our ability to properly anticipate and satisfy customer needs, adapt to new technologies, obtain regulatory approvals on a timely basis, demonstrate satisfactory clinical results, manufacture products in an economic and timely manner, engage qualified distributors for different territories and establish our sales force to sell our products, and differentiate our products from those of our competitors. If we cannot successfully introduce new products, adapt to changing technologies or anticipate changes in our current and potential customers' requirements, our products may become obsolete and our business could suffer.

Research and development efforts invested in our pipeline of specialty and other products may not achieve expected results.

We must invest increasingly significant resources to develop specialty products through our own efforts and through collaborations with third parties in the form of partnerships or otherwise. The development of specialty pharmaceutical products involves high-level processes and expertise and carries a significant risk of failure. For example, the average time from the pre-clinical phase to the commercial launch of a specialty pharmaceutical product can be 15 years or longer, and involves multiple stages: not only intensive preclinical, clinical and post clinical testing, but also highly complex, lengthy and expensive regulatory approval processes as well as reimbursement proceedings, which can vary from country to country. The longer it takes to develop a pharmaceutical product, the longer it may take for us to recover our development costs and generate profits, and, depending on various factors, we may not be able to ever recover such costs or generate profits.

During each stage of development, we may encounter obstacles that delay the development process and increase expenses, leading to significant risks that we will not achieve our goals and may be forced to abandon a potential product in which we have invested substantial amounts of time and money. These obstacles may include the following: preclinical-study failures; difficulty in enrolling patients in clinical trials; delays in completing formulation and other work needed to support an application for approval; adverse reactions or other safety concerns arising during clinical testing; insufficient clinical trial data to support the safety or efficacy of a product candidate; other failures to obtain, or delays in obtaining, the required regulatory approvals for a product candidate or the facilities in which a product candidate is manufactured; regulatory restrictions which may delay or block market penetration and the failure to obtain sufficient intellectual property rights for our products.

Accordingly, there can be no assurance that the continued development of our Inhaled AAT, Anti-SARS-CoV-2 IgG product and any other product candidate will be successful and will result in an FDA and/or EMA approvable indication.

Because of the amount of time and expense required to be invested in augmenting our pipeline of specialty and other products, including the unique know-how which may be required for such purpose, we may seek partnerships or joint ventures with third parties from time to time, and consequently face the risk that some or all of these third parties may fail to perform their obligations, or that the resulting arrangement may fail to produce the levels of success that we are relying on to meet our revenue and profit goals.

We rely on third parties to conduct our preclinical and clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may not obtain regulatory approval for, or commercialize, our product candidates in a timely manner or at all.

We rely upon third-party contractors, such as university researchers, study sites, physicians and contract research organizations ("CROs"), to conduct, monitor and manage data for our current and future preclinical and clinical programs. We expect to continue to rely on these parties for execution of our preclinical and clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on such third-party contractors does not relieve us of our regulatory responsibilities. With respect to clinical trials, we and our CROs are required to comply with current Good Clinical Practices ("GCP"), which are regulations and guidelines enforced by the FDA, the EMA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements.

These third-party contractors are not our employees, we cannot effectively control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs, and except for remedies available to us under our agreements with such third-party contractors, we may be unable to recover losses that result from any inadequate work on such programs. If such third-party contractors do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our development efforts and clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of such third-party contractors in the future, our business may be adversely affected.

We may not obtain orphan drug status for our products, or we may lose orphan drug designations, which would have a material adverse effect on our business.

One of the incentives provided by an orphan drug designation is market exclusivity for seven years in the United States and ten years in the European Union for the first product in a class approved for the treatment of a rare disease. Although several of our products and product candidates, including Inhaled AAT for AATD, have been granted the designation of an orphan drug, we may not be the first product licensed for the treatment of particular rare diseases in the future or our approved indication may vary from that subject to the orphan designation. In such cases we would not be able to take advantage of market exclusivity and instead another sponsor would receive such exclusivity.

Additionally, although the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same drug compound for the same indication, such exclusivity would not apply in the case that a subsequent sponsor could demonstrate clinical superiority or a market shortage occurs and would not prevent other sponsors from obtaining approval of the same compound for other indications or the use of other types of drugs for the same use as the orphan drug. In the event we are unable to fill demand for any orphan drug, it is possible that the FDA or the EMA may view such unmet demand as a market shortage, which could impact our market exclusivity.

The FDA and the EMA may also, in the future, revisit any orphan drug designation that they have respectively conferred upon a drug and retain the ability to withdraw the relevant designation at any time. Additionally, the U.S. Congress has considered, and may consider in the future, legislation that would restrict the duration or scope of the market exclusivity of an orphan drug, and, thus, we cannot be sure that the benefits to us of the existing statute in the United States will remain in effect. Furthermore, some court decisions have raised questions about FDA's interpretation of the orphan drug exclusivity provisions, which could potentially affect our ability to secure orphan drug exclusivity.

If we lose our orphan drug designations or fail to obtain such designations for our new products and product candidates, our ability to successfully market our products could be significantly affected, resulting in a material adverse effect on our business and results of operations.

The commercial success of the products that we may develop, if any, will depend upon the degree of market acceptance by physicians, patients, healthcare payors, opinion leaders, patients' organizations and others in the medical community that any such product obtains.

Any products that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors, opinion leaders, patients' organizations and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenue and we may not sustain profitability. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, some of which are beyond our control, including:

- the prevalence and severity of any side effects;

- the efficacy, potential advantages and timing of introduction to the market of alternative treatments;
- our ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration of our products;
- the willingness of physicians to prescribe our products;
- the willingness of patients to use our products;
- the strength of marketing and distribution support; and
- third-party coverage or reimbursement.

If we are not successful in achieving market acceptance for any new products that we have developed and that have been approved for commercial sale, we may be unable to recover the large investment we will have made and have committed ourselves to making in research and development efforts and our growth strategy will be adversely affected.

Each inhaled formulation of AAT, including Inhaled AAT for AATD, is being developed with a specific nebulizer produced by PARI, and the occurrence of an adverse market event or PARI's non-compliance with its obligations would have a material adverse effect on the commercialization of any inhaled formulation of AAT.

We are dependent upon PARI GmbH ("PARI") for the development and commercialization of any inhaled formulation of AAT, including our Inhaled AAT for AATD. We have an agreement with PARI, pursuant to which it is required to obtain the appropriate clearance to market PARI's proprietary eFlow® device, which is a device required for the administration of inhaled formulation of AAT, from the EMA and FDA for use with Inhaled AAT for AATD. See "Item 4. Information on the Company — Strategic Partnerships — PARI." Failure of PARI to achieve these authorizations will have a material adverse effect on the commercialization of any inhaled formulation of AAT, including Inhaled AAT for AATD, which would harm our growth strategy.

Additionally, pursuant to the agreement, PARI is obligated to manufacture and supply all of the market demand for the eFlow device for use in conjunction with any inhaled formulation of AAT and we are required to purchase all of our volume requirements from PARI. Any event that permanently, or for an extended period, prevents PARI from supplying the required quantity of devices would have an adverse effect on the commercialization of any inhaled formulation of AAT, including Inhaled AAT for AATD.

Risks Related to Our Operations and Industry

Product liability claims or product recalls involving our products, or products we distribute, could have a material adverse effect on our business.

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, distribution and sale of our Proprietary and Distribution products and other drug products. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and an even greater risk when we commercially sell any products, including those manufactured by others that we distribute in Israel. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, or if the indemnities we have negotiated do not adequately cover losses, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our Proprietary and Distribution products and any product candidates that we may develop;
- injury to our reputation;
- difficulties in recruitment of new participants to our future clinical trials and withdrawal of current clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- difficulties in finding distributors for our products;
- difficulties in entering into strategic partnerships with third parties;
- diversion of management's attention;
- loss of revenue;
- the inability to commercialize any products that we may develop; and
- higher insurance premiums.

Plasma is biological matter that is capable of transmitting viruses, infections and pathogens, whether known or unknown. Therefore, plasma derivative products, if not properly tested, inactivated, processed, manufactured, stored and transported, could cause serious disease and possibly death to the patient. Further, even when such steps are properly affected, viral and other infections may escape detection using current testing methods and may not be susceptible to inactivation methods. Any transmission of disease through the use of one of our products or third-party products sold by us could result in claims against us by or on behalf of persons allegedly infected by such products.

In addition, we sell and distribute third-party products in Israel, and the laws of Israel could also expose us to product liability claims for those products. Furthermore, the presence of a defect (or a suspicion of a defect) in a product could require us to carry out a recall of such product. A product liability claim or a product recall could result in substantial financial losses, negative reputational repercussions, loss of business and an inability to retain customers. Although we maintain insurance for certain types of losses, claims made against our insurance policies could exceed our limits of coverage or be outside our scope of coverage. Additionally, as product liability insurance is expensive and can be difficult to obtain, a product liability claim could increase our required premiums or otherwise decrease our access to product liability insurance on acceptable terms. In turn, we may not be able to maintain insurance coverage at a reasonable cost and may not be able to obtain insurance coverage that will be adequate to satisfy liabilities that may arise.

Regulatory approval for our products is limited by the FDA, EMA the IMOH and similar authorities in other jurisdictions to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and the prescription or promotion of off-label uses could adversely affect our business.

Any regulatory approval of our Proprietary and Distribution products is limited to those specific diseases and indications for which our products have been deemed safe and effective by the FDA, EMA, the IMOH or similar authorities in other jurisdictions. In addition to the regulatory approval required for new formulations, any new indication for an approved product also requires regulatory approval. Once we produce a plasma-derived protein therapeutic, we rely on physicians to prescribe and administer it as the product label directs and for the indications described on the labeling. To the extent any off-label (i.e., unapproved) uses and departures from the approved administration directions become pervasive and produce results such as reduced efficacy or other adverse effects, the reputation of our products in the marketplace may suffer. In addition, off-label uses may cause a decline in our revenues or potential revenues, to the extent that there is a difference between the prices of our product for different indications.

Furthermore, while physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA, EMA, the IMOH or other regulators. Although regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow FDA, EMA, the IMOH or similar authorities in other jurisdictions rules and guidelines relating to promotion and advertising can lead to other negative consequences that could hurt us, such as the suspension or withdrawal of an approved product from the market, enforcement letters, and corrective actions. Other regulatory authorities may impose separately penalties including, but not limited to, fines, disgorgement of money, operating restrictions, or criminal prosecution.

Regulatory inspections or audits conducted by regulatory bodies and our partners may lead to monetary losses and inability to adequately manufacture or sell our products.

The regulatory authorities, including the FDA, EMA, the IMOH, as well as our partners may, at any time and from time to time, audit or inspect our facilities. Such audits or inspections may lead to disruption of work, and if we fail to pass such audits or inspections, the relevant regulatory authority or partner may require remedial measures that may be costly or time consuming for us to implement, and may result in the temporary or permanent suspension of the manufacture, sale and distribution of our products.

The loss of one or more of our key employees could harm our business.

We depend on the continued service and performance of our key employees, including Amir London, our Chief Executive Officer and our other senior management staff. We have entered into employment agreements with all of our senior management, including Mr. London, and other key employees. Either party, however, can terminate these agreements for any reason. The loss of key members of our executive management team could disrupt our operations, commercial and business development activities, or product development and have an adverse effect on our ability to meet our targets and grow our business.

Our ability to attract, recruit, retain and develop qualified employees is critical to our success and growth.

We compete in a market that involves rapidly changing technological and regulatory developments that require a wide-ranging set of expertise and intellectual capital. In order for us to successfully compete and grow, we must attract, recruit, retain and develop the necessary personnel who can provide the needed expertise across the entire spectrum of our intellectual capital needs. While we have a number of our key personnel who have substantial experience with our operations, we must also develop and exercise our personnel to provide succession plans capable of maintaining continuity in the midst of the inevitable unpredictability of human capital. However, the market for qualified personnel is competitive, and we may not succeed in recruiting additional experienced or professional personnel, retaining current personnel or effectively replacing current personnel who depart with qualified or effective successors. Many of the companies with which we compete for experienced personnel have greater resources than us.

Our effort to retain and develop personnel may also result in significant additional expenses, which could adversely affect our profitability. There can be no assurance that qualified employees will continue to be employed or that we will be able to attract and retain qualified personnel in the future. Failure to retain or attract qualified personnel could have a material adverse effect on our business, financial condition and results of operations.

We are subject to risks associated with doing business globally.

Our operations are subject to risks inherent to conducting business globally and under the laws, regulations and customs of various jurisdictions and geographies. These risks include fluctuations in currency exchange rates, changes in exchange controls, loss of business in government and public tenders that are held annually in many cases, nationalization, expropriation and other governmental actions, availability of raw materials, changes in taxation, importation limitations, export control restrictions, changes in or violations of applicable laws, including the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.K. Bribery Act of 2010, pricing restrictions, economic and political instability, disputes between countries, diminished or insufficient protection of intellectual property, and disruption or destruction of operations in a significant geographic region regardless of cause, including war, terrorism, riot, civil insurrection or social unrest. Failure to comply with, or material changes to, the laws and regulations that affect our global operations could have an adverse effect on our business, financial condition or results of operations.

Laws and regulations governing the conduct of international operations may negatively impact our development, manufacture and sale of products outside of the United States and require us to develop and implement costly compliance programs.

We must comply with numerous laws and regulations in Israel and in each of the other jurisdictions in which we operate or plan to operate. The creation and implementation of any required compliance programs is costly, and the programs are often difficult to enforce, particularly where we must rely on third parties.

For example, the FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also requires companies whose securities are listed in the United States to comply with certain accounting provisions. For example, such companies must maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice, and the SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA and similar laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered as foreign officials. Additionally, pharmaceutical products are usually marketed by the local distributors through government tenders, and the majority of pharmaceutical companies' clients are HMOs which are foreign government officials under the FCPA. Certain payments to hospitals in connection with clinical trials and other work, and certain payments to HMOs have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, the SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to foreign currency exchange risk.

We receive payment for our sales and make payments for resources in a number of different currencies. While our sales and expenses are primarily denominated in U.S. dollars, our financial results may be adversely affected by fluctuations in currency exchange rates as a portion of our sales and expenses are denominated in other currencies, including the NIS and the Euro. Market volatility and currency fluctuations may limit our ability to cost-effectively hedge against our foreign currency exposure and, in addition, our ability to hedge our exposure to currency fluctuations in certain emerging markets may be limited. Hedging strategies may not eliminate our exposure to foreign exchange rate fluctuations and may involve costs and risks of their own, such as devotion of management time, external costs to implement the strategies and potential accounting implications. Foreign currency fluctuations, independent of the performance of our underlying business, could lead to materially adverse results or could lead to positive results that are not repeated in future periods.

Events in global credit markets may impact our ability to obtain financing or increase the cost of future financing, including interest rate fluctuations based on macroeconomic conditions that are beyond our control.

During periods of volatility and disruption in the U.S., European, Israeli or global credit markets, obtaining additional or replacement financing may be more difficult and the cost of issuing new debt could be higher than the costs we incur under our current debt. The higher cost of new debt may limit our ability to have cash on hand for working capital, capital expenditures and acquisitions on terms that are acceptable to us.

Developments in the economy may adversely impact our business.

Our operating and financial performance may be adversely affected by a variety of factors that influence the general economy in the United States, Europe, Israel, Russia, Latin America, Asia and other territories worldwide, including global and local economic slowdowns, challenges faced banks and the health of markets for the sovereign debt. Many of our largest markets, including the United States, Latin America and states that are members of the Commonwealth of Independent States previously experienced dramatic declines in the housing market, high levels of unemployment and underemployment, and reduced earnings, or, in some cases, losses, for businesses across many industries, with reduced investments in growth.

A recessionary economic environment may adversely affect demand for our plasma-derived protein therapeutics. As a result of job losses, patients in the U.S. and other markets may lose medical insurance and be unable to purchase needed medical products or may be unable to pay their share of deductibles or co-payments. Hospitals may steer patients adversely affected by the economy to less costly therapies, resulting in a reduction in demand, or demand may shift to public health hospitals, which purchase our products at a lower government price. A recessionary economic environment may also lead to price pressure for reimbursement of new drugs, which may adversely affect the demand for our future plasma-derived protein therapeutics.

If our manufacturing facility in Beit Kama, Israel were to suffer a serious accident, contamination, force majeure event (including, but not limited to, a war, terrorist attack, earthquake, major fire or explosion etc.) materially affecting our ability to operate and produce saleable plasma-derived protein therapeutics, all of our manufacturing capacity could be shut down for an extended period.

We rely on a single manufacturing facility in Beit Kama, which is located in southern Israel, approximately 20 miles east of the Gaza Strip. All of our revenues in our Proprietary Products segment as well as future revenues from contract manufacturing services to be performed by us for any third party partner, are derived from products manufactured at this facility and some of the products that are imported by us under our Distribution segment, are packed and stored in this manufacturing facility. If this facility were to suffer an accident or a force majeure event such as war, terrorist attack, earthquake, major fire or explosion, major equipment failure or power failure lasting beyond the capabilities of our backup generators or similar event, or contamination, our revenues would be materially adversely affected. In this situation, our manufacturing capacity could be shut down for an extended period, we could experience a loss of raw materials, work in process or finished goods and imported products inventory and our ability to operate our business would be harmed. In addition, in any such event, the reconstruction of our manufacturing facility and storage facilities, and the regulatory approval of the new facilities could be time-consuming. During this period, we would be unable to manufacture our plasma-derived protein therapeutics.

Our insurance against property damage and business interruption insurance may be insufficient to mitigate the losses from any such accident or force majeure event. We may also be unable to recover the value of the lost plasma or work-in-process inventories, as well as the sales opportunities from the products we would be unable to produce or distribute, or the loss of customers during such period.

Failure to adequately or timely adapt our manufacturing capacity to match changes in demand for our manufactured products and/or continued manufacturing at or close to our plant's maximum capacity may have a material adverse effect on our business.

Failure to adequately or timely adapt our manufacturing volume as needed or continued manufacturing at or close to our plant's maximum capacity levels may lead to an inability to supply products, may have an adverse effect on our business and could cause substantial harm to our business reputation and result in breach of our sales agreements and the loss of future customers and orders.

If we experience equipment difficulties or if the suppliers of our equipment or disposable goods fail to deliver key product components or supplies in a timely manner, our manufacturing ability would be impaired and our product sales could suffer.

For certain equipment and supplies, we depend on a limited number of companies that supply and maintain our equipment and provide supplies such as chromatography resins, filter media, glass bottles and stoppers used in the manufacture of our plasma-derived protein therapeutics. If our equipment were to malfunction, or if our suppliers stop manufacturing or supplying such machinery, equipment or any key component parts, the repair or replacement of the machinery may require substantial time and cost, and could disrupt our production and other operations. Alternative sources for key component parts or disposable goods may not be immediately available. In addition, any new equipment or change in supplied materials may require revalidation by us or review and approval by the FDA, the EMA, the IMOH or other regulatory authorities, which may be time-consuming and require additional capital and other resources. We may not be able to find an adequate alternative supplier in a reasonable time period, or on commercially acceptable terms, if at all. As a result, shipments of affected products may be limited or delayed. Our inability to obtain our key source supplies for the manufacture of products may require us to delay shipments of products, harm customer relationships and force us to curtail operations.

If our shipping or distribution channels were to become inaccessible due to an accident, act of terrorism, strike, epidemic or pandemic (such as the COVID-19 pandemic) or any other force majeure event, our supply, production and distribution processes could be disrupted.

Most of our Proprietary and Distribution products as well as most of the raw materials we utilize, including plasma and plasma derivatives, must be transported under controlled temperature conditions, including temperature of -20 degrees Celsius (-4 degrees Fahrenheit), to ensure the preservation of their proteins. Not all shipping or distribution channels are equipped to transport products or materials at these temperatures. If any of our shipping or distribution channels become inaccessible because of a serious accident, act of terrorism, strike, epidemic or pandemic (such as the COVID-19 pandemic) or any other force majeure event, we may experience disruptions in continued availability of plasma and other raw materials, delays in our production process or a reduction in our ability to distribute our Proprietary and Distribution products to our customers in the markets in which we operate.

A breakdown in our information technology (IT) systems could result in a significant disruption to our business.

Our operations are highly dependent on our information technology (IT) systems. If we were to suffer a breakdown in our systems, storage, distribution or tracing, we could experience significant disruptions affecting all our areas of activity, including our manufacturing, research, accounting and billing processes and potentially cause disruptions to our manufacturing process for products currently in production. We may also suffer from partial loss of information and data due to such disruption.

Our business and operations would suffer in the event of computer system failures, cyber-attacks on our systems or deficiency in our cyber security measures.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information and personal information, we could incur liability due to lost revenues resulting from the unauthorized use or theft of sensitive business information, remediation costs, and litigation risks including potential regulatory action by governmental authorities. In addition, any such disruption, security breach or other incident could delay the further development of our future product candidates due to theft or corruption of our proprietary data or other loss of information. Our business and operations could also be harmed by any reputational damage with customers, investors or third parties with whom we work, and our competitive position could be adversely impacted.

Failure to maintain the security of patient-related information or compliance with security requirements could damage our reputation with customers, cause us to incur substantial additional costs and become subject to litigation.

Pursuant to applicable privacy laws, we must comply with comprehensive privacy and security standards with respect to the use and disclosure of protected health information. If we do not comply with existing or new laws and regulations related to protecting privacy and security of personal or health information, we could be subject to monetary fines, civil penalties, or criminal sanctions. We may be required to comply with the data privacy and security laws of other countries in which we operate or from which we receive data transfers. For example, the General Data Protection Regulation ("GDPR") which took effect May 25, 2018, has broad application and enhanced penalties for noncompliance. The GDPR, which is wide-ranging in scope, governs the collection and use of personal data in the European Union and imposes operational requirements for companies that receive or process personal data of residents of the European Union. The GDPR may apply to our clinical development operations. In addition, the Israeli Privacy Protection Regulations (Information Security), 2017, which apply to our operations in Israel, require us to take certain security measures to secure the processing of personal data. We rely upon our CROs, third party contractors and distributors to process personal information on our behalf, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that their activities are conducted in accordance with privacy regulations and our reliance on such CROs, third-party contractors and distributors does not relieve us of our regulatory responsibilities. While we take reasonable and prudent steps to protect personal information and use such information in accordance with applicable privacy laws, a compromise in our security systems that results in personal information being obtained by unauthorized persons or our failure to comply with security requirements for financial transactions could adversely affect our reputation with our clients and result in litigation against us or the imposition of penalties, all of which may adversely impact our results of operations, financial condition and liquidity. In addition, given that the privacy laws and regulations in the jurisdictions in which we operate are new and subject to further judicial review and interpretation, it may be determined at a future time that although we take prudent measures to comply with such laws and regulations, such measures will not be sufficient to meet future elaborations or interpretations of such laws and regulations.

Uncertainty surrounding and future changes to healthcare law in the United States and other United States Government related mandates may adversely affect our business.

The healthcare regulatory environment in the U.S. is currently subject to significant uncertainty and the industry may in the future continue to experience fundamental change as a result of regulatory reform. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "healthcare reform law"), a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The healthcare reform law, among other things: (i) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) established annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. On April 1, 2016, final regulations issued by the Centers for Medicare and Medicaid Services to implement the changes to the Medicaid Drug Rebate Program under the healthcare reform law became effective. In addition, the new law established an abbreviated licensure pathway for products that are drugs made by a living organism or derived from a living organism, commonly referred to as biosimilars, to become FDA-approved biological products, with provisions covering exclusivity periods and a specific reimbursement methodology for biosimilars.

However, some provisions of the healthcare reform law have yet to be fully implemented, and former President Donald Trump vowed to repeal the healthcare reform law. On January 20, 2017, President Trump signed an executive order stating that the administration intended to seek prompt repeal of the healthcare reform law, and, pending repeal, directed the U.S. Department of Health and Human Services and other executive departments and agencies to take all steps necessary to limit any fiscal or regulatory burdens of the healthcare reform law. On October 12, 2017, President Trump signed another executive order directing certain federal agencies to propose regulations or guidelines to permit small businesses to form association health plans, expand the availability of short-term, limited duration insurance, and expand the use of health reimbursement arrangements, which may circumvent some of the requirements for health insurance mandated by the healthcare reform law. The U.S. Congress has also made several attempts to repeal or modify the healthcare reform law. In addition, there is ongoing litigation regarding the implementation and constitutionality of the healthcare reform law. While the law is still in effect pending the ultimate resolution of the litigation, the outcome of the litigation is unknown, and cannot be predicted. There is no guarantee whether the healthcare reform law will remain in effect or be repealed or replaced. In the coming years, additional changes could be made to U.S. governmental healthcare programs and U.S. healthcare laws that could significantly impact the success of our products. We cannot predict what other legislation relating to our business or to the health care industry may be enacted, or what effect such legislation may have on our business, prospects, operating results and financial condition.

In addition, federal, state and foreign governmental authorities are likely to continue efforts to control the price of drugs and reduce overall healthcare costs. For example, CMS issued an interim final rule on November 27, 2020 designed to test whether a Most-Favored-Nation model will help control growth in spending for Medicare Part B drugs without adversely affecting quality of care. This followed an Executive Order issued in September 2020 that directed the Secretary of DHHS to implement new payment models under the Medicare Part B and Part D programs to curb "unfair" and high drug prices in the United States. Implementation of this interim final rule has been blocked by a temporary restraining order and preliminary injunctions through various court actions. These efforts could have an adverse impact on our ability to market products and generate revenues in the United States and foreign countries.

On August 6, 2020, the former President of the United States Donald Trump issued the Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States (Executive Order 13944), which required the U.S. government to purchase "essential" medicines and medical supplies produced domestically, rather than abroad. Subsequently, on October 30, 2020 the FDA published a list of essential medicines, medical countermeasures, and critical inputs as required by Executive Order. The FDA has identified around 227 drugs and 96 devices, along with their respective critical inputs or active ingredients, that the FDA believes "are medically necessary to have available at all times" for the public health. Agencies across the federal government are expected to implement the "Buy American" priorities of the Executive Order through initiation of procurement strategies to help strengthen U.S. manufacturing capabilities and focus their efforts and attention on mobilizing domestic production of these specific items. This includes the FDA accelerating approval and clearance of domestically produced medicines and countermeasures, and it may also include contract awards to specific vendors to speed up domestic production. Rabies immune globulin, such as KEDRAB, is included in the list, and given that KEDRAB is manufactured outside the United States, implementation of the "Buy American" priorities of the Executive Order may affect our ability to continue selling the product to governmental agencies in the U.S. market or otherwise require us to invest in acquiring manufacturing capabilities for the product in the U.S., either directly or through contract manufacturing arrangements. The full effect of the implementation of the Executive Order on our commercial operations and results of operations cannot be currently estimated. On January 25, 2021, President Joe Biden signed a similar Executive Order to maximize the use of goods, products, materials produced in, and services offered in the United States. The Executive Order may affect FDA-related products.

We expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs.

Certain of our business practices could become subject to scrutiny by regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws governing our conduct in the United States are enforceable by criminal, civil and administrative penalties. Violations of laws such as the Federal Food, Drug and Cosmetic Act (the "FDCA"), the Federal False Claims Act (the "FCA"), the Public Health Service Act (the "PHS Act"), the Physician Payments Sunshine Act or a provision of the U.S. Social Security Act known as the "Anti-Kickback Law," or any regulations promulgated under their authority may result in jail sentences, fines or exclusion from federal and state health care programs, as may be determined by the Department of Health and Human Services, the Department of Defense, other federal and state regulatory authorities and the federal and state courts. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

For example, under the Anti-Kickback Law, and similar state laws and regulations, even common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose drugs and devices for patients, such as physicians and hospitals, can result in substantial legal penalties, including, among others, exclusion from Medicare and Medicaid programs, if those business arrangements are not appropriately structured; therefore, our arrangements with referral sources must be structured with care to comply with applicable requirements. Also, certain business practices, such as payment of consulting fees to healthcare providers, sponsorship of educational or research grants, charitable donations, interactions with healthcare providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits and reported in accordance with the Physician Payments Sunshine Act to avoid any possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or as a reward for past prescribing. Significant enforcement activity has been the result of actions brought by relators, who file complaints in the name of the United States (and if applicable, particular states) under federal and state False Claims Act statutes and can be entitled to receive a significant portion (often as great as 30%) of total recoveries. Also, violations of the False Claims Act can result in treble damages, and each false claim submitted can be subject to a penalty of up to $$23,331 per claim. Through the Physician Payments Sunshine Act, the healthcare reform law imposes reporting and disclosure requirements for pharmaceutical and medical device manufacturers with regard to a broad range of payments, ownership interests, and other transfers of value made to certain physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives and certain teaching hospitals. A number of states have similar laws in place and often require reporting for other categories of healthcare professionals, such as nurses. Additional and stricter prohibitions could be implemented by federal and state authorities. Where practices have been found to involve improper incentives to use products, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. Many manufacturers have been required to enter into consent decrees, corporate integrity agreements, or orders that prescribe allowable corporate conduct. Failure to satisfy requirements under the FDCA can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct.

To market and sell our products outside the United States, we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, and in such case, we would be precluded from commercializing products in those markets. In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Such trials may be time-consuming and expensive and may not show an advantage in cost-efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the United States or the European Union, we could be adversely affected. Also, under the FCPA, the United States has regulated conduct by U.S. businesses occurring outside of the United States, generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business.

To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as the Department of Health and Human Services' Office of Inspector General ("OIG"), have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. We have not adopted U.S. healthcare compliance and ethics programs that generally incorporate the HHS OIG's recommendations. Even if we do, having such a program can be no assurance that we will avoid any compliance issues.

We could be adversely affected if other government or private third-party payors decrease or otherwise limit the amount, price, scope or other eligibility requirements for reimbursement for the purchasers of our products.

Prices in many of our principal markets are subject to local regulation and certain pharmaceutical products, such as our Proprietary and Distribution products, are subject to price controls. In the United States, where pricing levels for our products are substantially established by third-party payors, a reduction in the payors' amount of reimbursement for a product may cause groups or individuals dispensing the product to discontinue administration of the product, to administer lower doses, to substitute lower cost products or to seek additional price-related concessions. These actions could have a negative effect on our financial results, particularly in cases where our products command a premium price in the marketplace or where changes in reimbursement rates induce a shift in the site of treatment. The existence of direct and indirect price controls and pressures over our products has affected, and may continue to materially adversely affect, our ability to maintain or increase gross margins.

Also, the intended use of a drug product by a physician can affect pricing. Physicians frequently prescribe legally available therapies for uses that are not described in the product's labeling and that differ from those tested in clinical studies and approved by the FDA or similar regulatory authorities in other countries. These off-label uses are common across medical specialties, and physicians may believe such off-label uses constitute the preferred treatment or treatment of last resort for many patients in varied circumstances. Reimbursement for such off-label uses is often not allowed by government payors. If reimbursement for off-label uses of products is not allowed by Medicare or other third-party payors, including those in the United States or the European Union, we could be adversely affected. For example, CMS could initiate an administrative procedure known as a National Coverage Determination ("NCD"), by which the agency determines which uses of a therapeutic product would be reimbursable under Medicare and which uses would not. This determination process can be lengthy, thereby creating a long period during which the future reimbursement for a particular product may be uncertain.

Current and future accounting pronouncements and other financial reporting standards, especially but not only concerning revenue recognition, might negatively impact our financial results.

We regularly monitor our compliance with applicable financial reporting standards and review new pronouncements and drafts thereof that are relevant to us. As a result of new standards, changes to existing standards, including but not limited to IFRS 15 on revenue from contracts with customers that we adopted in 2018 and IFRS 16 on leases that we adopted in 2019 and changes in their interpretation, we might be required to change our accounting policies, particularly concerning revenue recognition, to alter our operational policies so that they reflect new or amended financial reporting standards, or to restate our published financial statements. Such changes might have an adverse effect on our reputation, business, financial position, and profit, or cause an adverse deviation from our revenue and operating profit target.

We are subject to extensive environmental, health and safety, and other laws and regulations.

Our business involves the controlled use of hazardous materials, various biological compounds and chemicals. The risk of accidental contamination or injury from these materials cannot be eliminated. If an accident, spill or release of any regulated chemicals or substances occurs, we could be held liable for resulting damages, including for investigation, remediation and monitoring of the contamination, including natural resource damages, the costs of which could be substantial. In addition, some of the license and permits granted to us may be suspended or revoked, resulting in our inability to conduct our regular business activity, manufacture and/or distribute our products for an extended period of time or until we take remedial actions. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials and chemicals. Although we maintain workers' compensation insurance to cover the costs and expenses that may be incurred because of injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Additional or more stringent federal, state, local or foreign laws and regulations affecting our operations may be adopted in the future. We may incur substantial capital costs and operating expenses and may be required to obtain consents to comply with any of these or certain other laws or regulations and the terms and conditions of any permits required pursuant to such laws and regulations, including costs to install new or updated pollution control equipment, modify our operations or perform other corrective actions at our respective facilities. In addition, fines and penalties may be imposed for noncompliance with environmental, health and safety and other laws and regulations or for the failure to have, or comply with the terms and conditions of, required environmental or other permits or consents. We are subject to future audits by the Environmental Health Department of the Regional Health Bureau of the IMOH and the Ministry of Environmental Protection of Israel and may be required to perform certain actions from time to time in order to comply with these guidelines and their requirements. We do not expect the costs of complying with these guidelines to be material to our business. See "Item 4. Information on the Company — Environmental."

Under the Israeli Economic Competition Law, 5758-1988, as amended (the "Competition Law"), a company that supplies or acquires more than 50% of any product or service in Israel in a relevant market may be deemed to be a monopoly. In addition, any company that has "significant market power" (within the meaning of the Competition Law), even if it does not hold market share that is greater than 50%, shall be deemed to be a monopolist under the Competition Law. A monopolist is prohibited from participating in certain business practices, including unreasonably refusing to sell products or provide services over which a monopoly exists, charging unfair prices for such products or services, and abusing its position in the market in a manner that might reduce business competition or harm the public. In addition, the General Director of the Israeli Competition Authority may determine that a company is a monopoly and has the right to order such company to change its conduct in matters that may adversely affect business competition or the public, including by imposing restrictions on its conduct. Depending on the analysis and the definition of the different products we distribute in the markets in which we operate, we may be deemed to be a "monopoly" under the Competition Law with respect to certain of our products. Furthermore, following an amendment to the Competition Law that became effective in August 2015, which repealed the statutory exemption that existed under the Competition Law for restrictive arrangements that were mutually exclusive arrangements, we may face difficulties in certain cases negotiating distribution agreements with foreign pharmaceutical manufacturers.

We have entered into a collective bargaining agreement with the employees' committee and the Histadrut (General Federation of Labor in Israel), and we have incurred and could in the future incur labor costs or experience work stoppages or labor strikes as a result of any disputes in connection with such agreement.

In December 2013, we signed a collective bargaining agreement with the employees' committee established by our employees at our Beit Kama production facility in Israel and the Histadrut (General Federation of Labor in Israel) ("Histadrut"), which expired in December 2017. In November 2018, we signed a new collective bargaining agreement with the employees' committee and the Histadrut, which will expire in December 2021. We have experienced labor disputes and work stoppages in the past and in July 2018, during the course of our negotiations with the Histadrut and the employees' committee on the extension of the initial collective bargaining agreement beyond the December 2017 expiration, the employee's committee commenced a labor strike, which continued for approximately one month. As a result of the labor strike, in the year ended December 31, 2018, we had a $1.8 million write-off of indirect manufacturing costs and $0.8 million of process materials scraps. In December 2020, during the course of our negotiations with the Histadrut and the employees' committee on severance remuneration for employees who may be laid-off as part of the workforce down-sizing planned for 2021 as a result of the transfer of GLASSIA manufacturing to Takeda, the employee's committee declared a labor dispute, which was subsequently concluded during February 2021 following the execution of a special collective bargaining agreement governing such severance terms. Any future disputes with the employees' committee and the Histadrut over the implementation or the interpretation or the renewal of the collective bargaining agreement may lead to additional labor costs and/or work stoppages, which could adversely affect our business operations, including through a loss of revenue and strained relationships with customers.

Tax legislation in the United States may impact our business.

Changes to the Internal Revenue Code, the issuance of administrative rulings or court decisions could impact our business. On December 22, 2017, federal tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "TCJA") was signed into law. The TCJA provides for significant and wide-ranging changes to the U.S. Internal Revenue Code. Although significant guidance has been issued under the TCJA, many aspects of such legislation that could affect our business remain subject to considerable uncertainty. Further, it is impossible to predict the occurrence or timing of any additional tax legislation or other changes in tax law that materially affect our business or investors. For example, U.S. President Biden has put forth a tax plan that, if passed, could have a significant impact on tax rates and the availability of deductions applicable to trades or businesses. While, at this point, we cannot predict the likelihood of U.S. tax reform in 2021 or beyond, or the specific changes that may be enacted, if U.S. tax reform legislation moves forward, there may be an adverse impact to our business and investors.

Risks Related to Intellectual Property

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property relating to or incorporated into our technology and products, including the patents protecting our manufacturing process.

Our success depends in large part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology and products, especially intellectual property related to our manufacturing processes. At present, we consider our patents relating to our manufacturing process to be material to the operation of our business as a whole.

However, the patent landscape in the biotechnology and pharmaceutical fields is highly complicated and uncertain and involves complex legal, factual and scientific questions. Changes in either patent laws or in the interpretation of patent laws in the United States and other countries may diminish the value and strength of our intellectual property or narrow the scope of our patent protection. In addition, we may fail to apply for or be unable to obtain patents necessary to protect our technology or products or enforce our patents due to lack of information about the exact use of our processes by third parties. Even if patents are issued to us or to our licensors, they may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to prevent competitors from using similar technology or marketing similar products, or limit the length of time our technologies and products have patent protection. Additionally, many of our patents relate to the processes we use to produce our products, not to the products themselves. In many cases, the plasma-derived products we produce or intend to develop in the future will not, in and of themselves, be patentable. Since many of our patents relate to processes or uses of the products obtained therefrom, if a competitor is able to utilize a process that does not rely on our protected intellectual property, that competitor could sell a plasma-derived product similar to one we have developed or sell it without infringing these patents.

Patent rights are territorial; thus, any patent protections we have will only be enforceable in those countries in which we have issued patents. In addition, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the U.S. and the European Union. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that do not recognize or provide enforcement mechanisms for our patents. Furthermore, it is not possible to know the scope of claims that will be allowed in pending applications or which claims of granted patents, if any, will be deemed enforceable in a court of law.

Due to the extensive time needed to develop, test and obtain regulatory approval for our therapeutic candidates or any product we may sell or market, any patents that protect our therapeutic candidates or any product we may sell or market may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us. Following patent expiration, we may face increased competition through the entry of recombinant or generic products into the market and a subsequent decline in market share and profits.

In some cases we may rely on our licensors or partners to conduct patent prosecution, patent maintenance or patent defense on our behalf. Therefore, our ability to ensure that these patents are properly prosecuted, maintained, or defended may be limited, which may adversely affect our rights in our therapeutic candidates and potential approved for marketing products. Any failure by our licensors or development or commercialization partners to properly conduct patent prosecution, maintenance, enforcement, or defense could materially harm our ability to obtain suitable patent protection covering our therapeutic candidates or products or ensure freedom to commercialize the products in view of third-party patent rights, thereby materially reducing our potential profits.

Our patents also may not afford us protection against competitors or other third parties with similar technology. Because patent applications worldwide are typically not published until 18 months after their filing, and because publications of discoveries in scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to file for protection of the inventions set forth in such patent applications. As a result, the patents we own and license may be invalidated in the future, and the patent applications we own and license may not be granted. Moreover, in the US, during 2012, the Leahy-Smith America Invents Act ("AIA") created a new legal proceeding, the *inter partes review* petition, that allows third parties to challenge the validity of patents before the Patent Trials and Appeals Board.

The costs of these proceedings could be substantial and our efforts in them could be unsuccessful, resulting in a loss of our anticipated patent position. In addition, if a third party prevails in such a proceeding and obtains an issued patent, we may be prevented from practicing technology or marketing products covered by that patent. Additionally, patents and patent applications owned by third parties may prevent us from pursuing certain opportunities such as entering into specific markets or developing or commercializing certain products or reducing the cost effectiveness of the relevant business as a result of needing to make royalty payments or other business conciliations. Finally, we may choose to enter into markets where certain competitors have patents or patent protection over technology that may impede our ability to compete effectively.

Our patents are due to expire at various dates between 2024 and 2040. However, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting advantages of the patent. Our pending and future patent applications may not lead to the issuance of patents or, if issued, the patents may not be issued in a form that will provide us with any competitive advantage. We also cannot guarantee that: any of our present or future patents or patent claims or other intellectual property rights will not lapse or be invalidated, circumvented, challenged or abandoned; our intellectual property rights will provide competitive advantages or prevent competitors from making or selling competing products; our ability to assert our intellectual property rights against potential competitors or to settle current or future disputes will not be limited by our agreements with third parties; any of our pending or future patent applications will be issued or have the coverage originally sought; our intellectual property rights will be enforced in jurisdictions where competition may be intense or where legal protection may be weak; or we will not lose the ability to assert our intellectual property rights against, or to license our technology to, others and collect royalties or other payments. In addition, our competitors or others may design around our patents or protected technologies. Effective protection of our intellectual property rights may also be unavailable, limited or not applied in some countries, and even if available, we may fail to pursue or obtain necessary intellectual property protection in such countries. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents and other intellectual property rights, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims, apply certain patent or other regulatory procedures or file lawsuits against third parties. Such proceedings could entail significant costs to us and divert our management's attention from developing and commercializing our products. Lawsuits may ultimately be unsuccessful, and may also subject us to counterclaims and cause our intellectual property rights to be challenged, narrowed, invalidated or held to be unenforceable.

Additionally, unauthorized use of our intellectual property may have occurred or may occur in the future, including, for example, in the production of counterfeit versions of our products. Counterfeit products may use different and possibly contaminated sources of plasma and other raw materials, and the purification process involved in the manufacture of counterfeit products may raise additional safety concerns, over which we have no control. Although we have taken steps to minimize the risk of unauthorized uses of our intellectual property, including for the production of counterfeit products, any failure to identify unauthorized use of, and otherwise adequately protect, our intellectual property could adversely affect our business, including reducing the demand for our products. Additionally, any reported adverse events involving counterfeit products that purported to be our products could harm our reputation and the sale of our products in particular and consumer willingness to use plasma-derived therapeutics in general. Moreover, if we are required to commence litigation related to unauthorized use, whether as a plaintiff or defendant, such litigation would be time-consuming, force us to incur significant costs and divert our attention and the efforts of our management and other employees, which could, in turn, result in lower revenue and higher expenses.

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how.

We rely on proprietary information (such as trade secrets, know-how and confidential information) to protect intellectual property that may not be patentable, or that we believe is best protected by means that do not require public disclosure. We generally seek to protect this proprietary information by entering into confidentiality agreements, or consulting, services, material transfer agreements or employment agreements that contain non-disclosure and non-use provisions, as well as ownership provisions, with our employees, consultants, service providers, contractors, scientific advisors and third parties. However, we may fail to enter into the necessary agreements, and even if entered into, these agreements may be breached or otherwise fail to prevent disclosure, third-party infringement or misappropriation of our proprietary information, may be limited as to their term and may not provide an adequate remedy in the event of unauthorized disclosure or use of proprietary information. We have limited control over the protection of trade secrets used by our third-party manufacturers, suppliers, other third parties which are granted with license to use our know-how and former employees and could lose future trade secret protection if any unauthorized disclosure of such information occurs. In addition, our proprietary information may otherwise become known or be independently developed by our competitors or other third parties. To the extent that our employees, consultants, service providers, contractors, scientific advisors and other third parties use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain protection for our proprietary information could adversely affect our competitive business position. Furthermore, laws regarding trade secret rights in certain markets where we operate may afford little or no protection to our trade secrets.

We also rely on physical and electronic security measures to protect our proprietary information, but we cannot provide assurance that these security measures will not be breached or provide adequate protection for our property. There is a risk that third parties may obtain and improperly utilize our proprietary information to our competitive disadvantage. We may not be able to detect or prevent the unauthorized use of such information or take appropriate and timely steps to enforce our intellectual property rights. See "*—Our business and operations would suffer in the event of computer system failures, cyber-attacks on our systems or deficiency in our cyber security measures*."

Changes in either U.S. or foreign patent law or in the interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

Our success, like the success of many other biotechnology companies, is heavily dependent on intellectual property and on patents in particular. The procurement and enforcement of patents in the biotechnology industry is complex from a technological and legal standpoint, and the process is therefore costly, time-consuming and inherently uncertain. In addition, on September 16, 2011, the AIA was signed into law. The AIA included a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application with the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. As a result of this change of law, if we do not promptly file a patent application at the time of a new product's invention, and if a third party subsequently invented and patented such product, we would lose our right to patent such invention.

The AIA also introduced new limitations on where a patentee may file a patent infringement suit and new opportunities for third parties to challenge any issued patent in the USPTO. Such changes apply to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings compared to the evidentiary standard in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents and enforce our existing and future patents.

If we are unable to protect our trademarks from infringement, our business prospects may be harmed.

We own trademarks that identify certain of our products, our business name and our logo, and have registered these trademarks in certain key markets. Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks could harm our reputation or commercial interests. In addition, our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and the outcome may be an inadequate remedy. Even if trademarks are issued to us or to our licensors, they may be challenged, narrowed, cancelled, held to be unenforceable or circumvented.

We may be subject to claims that we infringe, misappropriate or otherwise violate the intellectual property rights of third parties.

The conduct of our business, our Proprietary and/or Distribution products or product candidates may infringe or be accused of infringing one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may be subsequently issued and to which we do not hold a license or other rights. For example, certain of our competitors and other third parties own patents and patent applications in areas relating to critical aspects of our business and technology, including the separation and purification of plasma proteins, the composition of AAT, the use of AAT for different indications, and the distribution or use of recombinant or biosimilar pharmaceutical products, and these competitors may in the future allege that we are infringing on their patent rights. We may also be subject to claims that we are infringing, misappropriating or otherwise violating other intellectual property rights, such as trademarks, copyrights or trade secrets. Third parties could therefore bring claims against us or our strategic partners that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if such a claim were brought against us, our strategic partners or our manufacturer suppliers for Distribution products, we or they could be forced to permanently or temporarily stop or delay manufacturing, exportation or sales of such product or product candidate that is the subject of the dispute or suit.

In addition, we are a party to certain license agreements that may impose various obligations upon us as a licensee, including the obligation to bear the cost of maintaining the patents subject to the license and to make milestone and royalty payments. If we fail to comply with these obligations, the licensor may terminate the license, in which event we might not be able to market any product that is covered by the licensed intellectual property.

If we are found to be infringing, misappropriating or otherwise violating the patent or other intellectual property rights of a third party, or in order to avoid or settle claims, we or our strategic partners may choose or be required to seek a license, execute cross-licenses or enter into a covenant not to sue agreement from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we or our strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened claims, we or our strategic partners are unable to enter into licenses on acceptable terms.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition, to the extent that we gain greater visibility and market exposure as a public company in the United States, we face a greater risk of being involved in such litigation. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, opposition, cancellation, re-examination and similar proceedings before the USPTO and its foreign counterparts and other regulatory authorities, regarding intellectual property rights with respect to our products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace or to conduct our business in accordance with our plans and budget, and patent litigation and other proceedings may also absorb significant management time.

Some of our employees, consultants and service providers, were previously employed or hired at universities, medical institutes, or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. While we take steps to prevent them from using the proprietary information or know-how of others in their work for us, we may be subject to claims that we or they have inadvertently or otherwise used or disclosed intellectual property, trade secrets or other proprietary information of any such employee's former employer or former ordering service or that they have breached certain non-compete obligations to their former employers. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs to us or be distracting to our management. If we fail to defend any such claims successfully, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

Risks Related to Our Financial Position and Capital Resources

We have incurred significant losses since our inception and while we were profitable in the four years ended December 31, 2020, we may incur losses in the future and thus may never achieve sustained profitability.

As of December 31, 2020, our cash and cash equivalents and short-term investments were $109.3 million. Since inception, we have incurred significant operating losses. While our net profit was $17.1 million, $22.3 million and $22.3 million for the years ended December 31, 2020, 2019 and 2018, respectively, as of December 31, 2020, we had an accumulated deficit of $43.9 million. While we intend to take actions to address the expected reduction in sales and profitability as a result of the transition of GLASSIA manufacturing to Takeda, there can be no assurance that such actions will be successful and we may not be able to continue to generate profitability in future years.

Our business requires substantial capital, including potential investments in large capital projects, to operate and grow and to achieve our strategy of realizing increased operating leverage.

In order to obtain FDA, EMA and other regulatory approvals for product candidates and new indications for existing products, we may be required to enhance the facilities and processes by which we manufacture existing products, to develop new product delivery mechanisms for existing products, to develop innovative product additions and to conduct clinical trials. We face a number of obstacles that we will need to overcome in order to achieve our operating goals, including but not limited to the successful development of experimental products for use in clinical trials, the design of clinical study protocols acceptable to the FDA, the EMA and other regulatory authorities, the successful outcome of clinical trials, scaling our manufacturing processes to produce commercial quantities or successfully transition technology, obtaining FDA, EMA and other regulatory approvals of the resulting products or processes and successfully marketing an approved or new product with applicable new processes. To finance these various activities, we may need to incur future debt or issue additional equity. We may not be able to structure our debt obligations on favorable economic terms and any offering of additional equity would result in a dilution of the equity interests of our current shareholders. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

In addition, our manufacturing facility requires continued investment and upgrades. Moreover, any enhancements to our manufacturing facilities necessary to obtain FDA or EMA approval for product candidates or new indications for existing products could require large capital projects. We may also undertake such capital projects in order to maintain compliance with cGMP or expand capacity. Capital projects of this magnitude involve technology and project management risks. Technologies that have worked well in a laboratory or in a pilot plant may cost more or not perform as well, or at all, in full scale operations. Projects may run over budget or be delayed. We cannot be certain that any such project will be completed in a timely manner or that we will maintain our compliance with cGMP, and we may need to spend additional amounts to achieve compliance. Additionally, by the time multi-year projects are completed, market conditions may differ significantly from our initial assumptions regarding competitors, customer demand, alternative therapies, reimbursement and public policy, and as a result capital returns may not be realized. In addition, to fund large capital projects, we may similarly need to incur future debt or issue additional dilutive equity. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

Our current working capital may not be sufficient to complete our research and development with respect to any or all of our pipeline products or to commercialize our products.

As of December 31, 2020, we had cash and short-term investments of $109.3 million. We plan to fund our future operations through continued sale and distribution of our proprietary and distribution products, commercialization and or out-licensing of our pipeline product candidates, and as requires raising additional capital through the sale of equity or debt. These amounts may not be sufficient to complete the research and development of all of our candidates, and there can be no assurances of the financial success of our commercialization activities or our ability to access the equity and debt capital markets on terms acceptable to us, if at all. To the extent we are unable to fund our research and development, our future product development activities could be materially adversely affected.

Raising additional capital would cause dilution to our existing shareholders, and raising debt or funds through collaborations or strategic alliances and licensing arrangements may restrict our operations or require us to relinquish rights.

To the extent that we raise additional funds to fund our activities through the sale of equity or securities that are convertible into or exchangeable for, or that represent the right to receive, ordinary shares or substantially similar securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that are not favorable to us.

Risks Related to Our Ordinary Shares

The requirements of being a public company in the United States, as well as in Israel, may strain our resources and distract our management, which could make it difficult to manage our business and could have a negative effect on our results of operations and financial condition.

As a public company whose shares are being traded on Nasdaq and the Tel Aviv Stock Exchange (the "TASE"), we are required to comply with various regulatory and reporting requirements, including those required by the SEC. Complying with these reporting and regulatory requirements is time consuming, and may result in increased costs to us and could have a negative effect on our business, results of operations and financial condition. As a public company in the United States, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the requirements of the Sarbanes-Oxley Act of 2002 ("SOX"). These requirements may place a strain on our systems and resources. The Exchange Act requires that we file annual and current reports, and file or make public certain additional information, with respect to our business and financial condition. SOX requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. To maintain and improve the effectiveness of our disclosure controls and procedures, we may need to commit significant resources, hire additional staff and provide additional management oversight. These activities may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition and results of operations. Furthermore, as our business changes and if we expand either through acquisitions or by means of organic growth, our internal controls may become more complex and we will require significantly more resources to ensure our internal controls remain effective. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could adversely affect our operating results or cause us to fail to meet our reporting obligations. If we identify material weaknesses, the disclosure of that fact, even if quickly remediated, could reduce the market's confidence in our financial statements and negatively affect our share price.

Additionally, as of December 31, 2018, we were no longer an "emerging growth company," as defined in the JOBS Act, and are now required to comply with additional disclosure and reporting requirements, including, but not limited to, being required to comply with the auditor attestation requirements of Section 404 of SOX (and the rules and regulations of the SEC thereunder). These additional reporting requirements may increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to devote substantial time to these public company requirements.

Our share price may be volatile.

The market price of our ordinary shares is highly volatile and could be subject to wide fluctuations in price as a result of various factors, some of which are beyond our control. These factors include:

- actual or anticipated fluctuations in our financial condition and operating results;
- overall conditions in the specialty pharmaceuticals market;
- loss of significant customers or changes to agreements with our strategic partners;
- changes in laws or regulations applicable to our products;
- actual or anticipated changes in our growth rate relative to our competitors';
- announcements of clinical trial results, technological innovations, significant acquisitions, strategic alliances, joint ventures or capital commitments by us or our competitors;
- changes in key personnel;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- the issuance of new or updated research reports by securities analysts;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain intellectual property protection for our technologies;
- announcement of, or expectation of, additional financing efforts;
- sales of our ordinary shares by us or our shareholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- recalls and/or adverse events associated with our products;
- the expiration of contractual lock-up agreements with our executive officers and directors; and
- general political, economic and market conditions.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market price of equity securities of many companies. Broad market and industry fluctuations, as well as general economic, political and market conditions, may negatively impact the market price of our ordinary shares. For example, during the year ended December 31, 2020, in the wake of the COVID-19 pandemic, the stock market in general, including in the biotechnology/pharmaceutical sector, experienced extreme price and volume fluctuations. Specifically, our share's trading volume and price were extremely volatile, fluctuating more than twice their levels prior to the COVID-19 pandemic. Such volatility can be attributed to many factors, including our announcements of the development and progress of our Anti-SARS-CoV-2 IgG product as a potential treatment for COVID-19, our financial results and conditions and general market trends affected by the pandemic. Increases in price and volume may not be sustainable for a long period of time.

In the past, companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation or derivative actions. We, as well as our directors and officers, may also be the target of these types of litigation and actions in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our shares, our share price and trading volume could be negatively impacted.

The trading market for our ordinary shares may be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts, and we cannot provide any assurance that analysts will cover us or, if they do, provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding our shares, or provide more favorable relative recommendations about our competitors, our share price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could negatively impact our share price or trading volume.

Future sales of our ordinary shares in the public market could cause our share price to fall.

Sales by us or the shareholders of a substantial number of our ordinary shares in the public market, either on the TASE or Nasdaq, or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity securities. As of December 31, 2020, we had 44,742,963 ordinary shares outstanding.

Furthermore, except for shares held by our affiliates as contemplated by Rule 144 under the U.S. Securities Act of 1933, as amended (the "Securities Act"), all of the ordinary shares that are outstanding as of December 31, 2020, as well as the 1,660,958 ordinary shares issuable upon exercise of outstanding options and vesting of 104,519 restricted share units granted to certain officers and employees, are freely tradable in the United States without restrictions or further registration under the Securities Act. As of February 24, 2021, approximately 36% of our outstanding ordinary shares are beneficially owned by affiliates. These entities could resell the shares into the public markets in the United States in the future in accordance with the requirements of Rule 144, which include certain limitations on volume.

In addition, the FIMI Opportunity Funds own 9,452,708 of our outstanding ordinary shares (representing an ownership percentage of 21% of the outstanding shares and 20% on a fully diluted basis). Pursuant to a registration rights agreement we entered into with FIMI Opportunity Funds on January 20, 2020, they have "demand" and "piggyback" registration rights covering the ordinary shares of our company held by them. All shares of FIMI Opportunity Funds sold pursuant to an offering covered by a registration statement would be freely transferable. Sales of a substantial number of shares of our ordinary shares, or the perception that the FIMI Opportunity Funds may exercise their registration rights, could put downward pressure on the market price of our ordinary shares and could impair our future ability to raise capital through an offering of our equity securities.

The significant share ownership positions and board representation of the FIMI Opportunity Funds, Leon Recanati and Jonathan Hahn may limit our shareholders' ability to influence corporate matters.

The FIMI Opportunity Funds (three of whose partners are members of our board of directors, one of which serves as our Chairman), Leon Recanati and Jonathan Hahn, members of our board of directors, beneficially owned, directly and indirectly, approximately 21%, 8% and 4% of our outstanding ordinary shares, respectively, as of February 24, 2021. For additional information, see "Item 6. Directors, Senior Management and Employees — Share Ownership" and "Item 7. Major Shareholders and Related Party Transactions — Major Shareholders." Accordingly, the FIMI Opportunity Funds, Leon Recanati, and the Hahn family through their equity ownership and board representation, individually and collectively, have significant influence over the outcome of matters required to be submitted to our shareholders for approval, including decisions relating to the election of our board of directors and the outcome of any proposed acquisition, merger or consolidation of our company. Their interests may not be consistent with those of our other shareholders. In addition, these parties' significant interest in us may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our shares. On March 6, 2013, a shareholders agreement was entered into, effective March 4, 2013, pursuant to which Mr. Recanati and any company controlled by him (collectively, the "Recanati Group"), on the one hand, and Damar Chemicals Inc. ("Damar"), TUTEUR S.A.C.I.F.I.A ("Tuteur") (companies controlled by the Hahn family) and their affiliates (collectively, the "Damar Group"), on the other hand, have each agreed to vote the ordinary shares beneficially owned by them in favor of the election of director nominees designated by the other group as follows: (i) three director nominees, so long as the other group beneficially owns at least 7.5% of our outstanding share capital, (ii) two director nominees, so long as the other group beneficially owns at least 5.0% (but less than 7.5%) of our outstanding share capital, and (iii) one director nominee, so long as the other group beneficially owns at least 2.5% (but less than 5.0%) of our outstanding share capital. In addition, to the extent that after the designation of the foregoing director nominees there are additional director vacancies, each of the Recanati Group and Damar Group have agreed to vote the ordinary shares beneficially owned by them in favor of such additional director nominees designated by the party who beneficially owns the larger voting rights in our company. We are not party to such agreement or bound by its terms. As a result of such voting agreement, the Recanati Group and the Damar Group and their affiliates together have significant influence over the election of directors of the company.

Our ordinary shares are traded on more than one market and this may result in price variations.

Our ordinary shares have been traded on the TASE since August 2005, and on Nasdaq since May 2013. Trading in our ordinary shares on these markets takes place in different currencies (U.S. dollars on Nasdaq and NIS on the TASE), and at different times (as a result of different time zones, trading days and public holidays in the United States and Israel). The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of our ordinary shares on the TASE could cause a decrease in the trading price of our ordinary shares on Nasdaq, and a decrease in the price of our ordinary shares on Nasdaq could likewise cause a decrease in the trading price of our ordinary shares on the TASE.

Our U.S. shareholders may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, we would be characterized as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares, and having interest charges apply to distributions by us and the proceeds of share sales. See "Item 10. Additional Information — E. Taxation — United States Federal Income Taxation."

We are a "foreign private issuer" and have disclosure obligations that are different from those of U.S. domestic reporting companies. As a result, we may not provide you the same information as U.S. domestic reporting companies or we may provide information at different times, which may make it more difficult for you to evaluate our performance and prospects.

We are a foreign private issuer and, as a result, are not subject to the same requirements as U.S. domestic issuers. Under the Exchange Act, we are subject to reporting obligations that, in certain respects, are less detailed and/or less frequent than those of U.S. domestic reporting companies. For example, we are not required to issue quarterly reports, proxy statements that comply with the requirements applicable to U.S. domestic reporting companies, or individual executive compensation information that is as detailed as that required of U.S. domestic reporting companies. We also have four months after the end of each fiscal year to file our annual reports with the SEC and are not required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, our directors and executive officers will not be required to report equity holdings under Section 16 of the Exchange Act and will not be subject to the insider short-swing profit disclosure and recovery regime.

As a foreign private issuer, we are also exempt from the requirements of Regulation FD (Fair Disclosure) which, generally, are meant to ensure that select groups of investors are not privy to specific information about an issuer before other investors. However, we are still subject to the anti-fraud and anti-manipulation rules of the SEC, such as Rule 10b-5 under the Exchange Act. Since many of the disclosure obligations imposed on us as a foreign private issuer differ from those imposed on U.S. domestic reporting companies, you should not expect to receive the same information about us and at the same time as the information provided by U.S. domestic reporting companies.

As we are a "foreign private issuer" and follow certain home country corporate governance practices instead of otherwise applicable SEC and Nasdaq corporate governance requirements, our shareholders may not have the same protections afforded to shareholders of domestic U.S. issuers that are subject to all SEC and Nasdaq corporate governance requirements.

As a foreign private issuer, we have the option to, and we do, follow Israeli corporate governance practices rather than certain corporate governance requirements of Nasdaq, except to the extent that such laws would be contrary to U.S. securities laws, and provided that we disclose the requirements we are not following and describe the home country practices we follow instead. We have relied on this "foreign private issuer exemption" with respect to all the items listed under the heading "Item 16G. Corporate Governance," including with respect to shareholder approval requirements in respect of equity issuances and equity-based compensation plans, the requirement to have independent oversight on our director nominations process and to adopt a formal written charter or board resolution addressing the nominations process, the quorum requirement for meetings of our shareholders and the Nasdaq requirement to have a formal charter for the compensation committee. We may in the future elect to follow home country practices in Israel with regard to other matters. As a result, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all Nasdaq corporate governance requirements. See "Item 16G. Corporate Governance."

We have never paid cash dividends on our ordinary shares and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our ordinary shares will likely depend on whether the price of our ordinary shares increases, which may not occur.

We have never declared or paid any cash dividends on our ordinary shares and do not intend to pay any cash dividends. Any agreements that we may enter into in the future may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our ordinary shares. In addition, Israeli law limits our ability to declare and pay dividends, and may subject our dividends to Israeli withholding taxes. We anticipate that we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their ordinary shares after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

Risks Relating to Our Incorporation and Location in Israel

Conditions in Israel could adversely affect our business.

We are incorporated under Israeli law and our principal offices and manufacturing facilities are located in Israel. Accordingly, political, economic and military conditions in Israel directly affect our business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. Although Israel has entered into various agreements with Egypt, Jordan and the Palestinian Authority, there has been terrorist activity with varying levels of severity over the years. During July and August 2014, Israel engaged in an armed conflict with Hamas in the Gaza Strip, resulting in thousands of rockets being fired from the Gaza Strip and missile strikes against civilian targets in various parts of Israel, which disrupted most day-to-day civilian activity, particularly in southern Israel, the location of our manufacturing facility. In the event that our facilities are damaged as a result of hostile action or hostilities otherwise disrupt the ongoing operation of our facilities or the airports and seaports on which we depend to import and export our supplies and products, our ability to manufacture and deliver products to customers could be materially adversely affected. Additionally, the operations of our Israeli suppliers and contractors may be disrupted as a result of hostile action or hostilities, in which event our ability to deliver products to customers may be materially adversely affected.

Several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in Israel or political instability in the region continues or increases. These restrictions may limit materially our ability to obtain raw materials from these countries or sell our products to companies in these countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or significant downturn in the economic or financial condition of Israel, could adversely affect our operations and product development, cause our sales to decrease and adversely affect the share price of publicly traded companies having operations in Israel, such as us.

Further, on Israel's domestic front there is currently a level of unprecedented political instability. The Israeli government has been in a transitionary phase since December of 2018, when the Israeli Parliament, or the Knesset, first resolved to dissolve itself and call for new general elections. In 2019, Israel held general elections twice – in April and September – and a third general election was held on March 2, 2020. The Knesset, for reasons related to this extended political transition, has failed to pass a budget for the year 2020, and certain government ministries are left without necessary resources and may not receive sufficient funding moving forward. During December 2020, the government was unable to pass a budget by the applicable deadline, triggering a snap election expected to take place during March 2021. Actual or perceived political instability in Israel or any negative changes in the political environment, may individually or in the aggregate adversely affect the Israeli economy and, in turn, our business, financial condition, results of operations, and prospects.

Our operations may be disrupted by the obligations of personnel to perform military service.

As of December 31, 2020, we had 408 employees, all of whom were based in Israel. Certain of our employees may be called upon to perform up to 36 days (and in some cases more) of annual military reserve duty until they reach the age of 40 (and in some cases, up to 45 or older) and, in emergency circumstances, could be called to active duty. In response to increased tension and hostilities, there have been occasional call-ups of military reservists, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees related to their, or their spouse's, military service or the absence for extended periods of one or more of our key employees for military service. Such disruption could materially adversely affect our business and results of operations. Additionally, the absence of a significant number of the employees of our Israeli suppliers and contractors related to military service or the absence for extended periods of one or more of their key employees for military service may disrupt their operations, in which event our ability to deliver products to customers may be materially adversely affected.

The tax benefits under Israel tax legislation that are available to us require us to continue to meet various conditions and may be terminated or reduced in the future, which could increase our costs and taxes.

One of our Israeli facilities was granted "Approved Enterprise" status by the Investment Center of the Ministry of Economy and Industry (formerly named the Ministry of Industry, Trade and Labor) of the State of Israel (the "Investment Center"), under the Israeli Law for the Encouragement of Capital Investments, 1959 (the "Investment Law"), which made us eligible for a grant and certain tax benefits under that law for a certain investment program. The investment program provided us with a grant in the amount of 24% of our approved investments, in addition to certain tax benefits, which applied to the turnover resulting from the operation of such investment program, for a period of up to ten consecutive years from the first year in which we generated taxable income. The tax benefits under the Approved Enterprise status expired at the end of 2017.

Additionally, we have obtained a tax ruling from the Israel Tax Authority according to which, among other things, our activity has been qualified as an "industrial activity," as defined in the Investment Law, and is also eligible for tax benefits as a "Privileged Enterprise," which apply to the turnover attributed to such enterprise, for a period of up to ten years from the first year in which we generated taxable income. The tax benefits under the Privileged Enterprise status are scheduled to expire at the end of 2023.

In order to remain eligible for the tax benefits of a Privileged Enterprise, we must continue to meet certain conditions stipulated in the Investment Law and its regulations, as amended, and must also comply with the conditions set forth in the tax ruling. These conditions include, among other things, that the production, directly or through subcontractors, of all our products should be performed within certain regions of Israel. If we do not meet these requirements, the tax benefits would be reduced or canceled and we could be required to refund any tax benefits that we received in the past, in whole or in part, linked to the Israeli consumer price index, together with interest. Further, these tax benefits may be reduced or discontinued in the future. For example, while we do not expect that the transfer of manufacturing of GLASSIA to Takeda, or the grant to Takeda of the right to use our technology for such manufacturing, would result in the reduction or loss of these tax benefits, according to the tax ruling that we obtained, we may lose those benefits if it is determined that we do not comply with the conditions set forth in the tax ruling. If these tax benefits are canceled, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies was 25% in 2016, it decreased to 24% in 2017 and further decreased to 23% in 2018 and thereafter. For more information about applicable Israeli tax regulations, see "Item 10. Additional Information — E. Taxation — Israeli Tax Considerations and Government Programs."

In the future, we may not be eligible to receive additional tax benefits under the Investment Law if we increase certain of our activities outside of Israel. Additionally, in the event of a distribution of a dividend from the abovementioned tax exempt income, in addition to withholding tax at a rate of 20% (or a reduced rate under an applicable double tax treaty), we will be subject to tax on the otherwise exempt income (grossed-up to reflect the pre-tax income that we would have had to earn in order to distribute the dividend) at the corporate tax rate applicable to our Approved/Privileged Enterprise's income, which would have been applied had we not enjoyed the exemption. Similarly, in the event of our liquidation or a share buyback, we will be subject to tax on the grossed up amount distributed or paid at the corporate tax rate which would have been applied to our Privileged Enterprise's income had we not enjoyed the exemption. For more information about applicable Israeli tax regulations, see "Item 10. Additional Information — E. Taxation — Israeli Tax Considerations and Government Programs."

Tax matters, including changes in tax laws, adverse determinations by taxing authorities and imposition of new taxes could adversely affect our results of operations and financial condition. Furthermore, we may not be able to fully utilize our net operating loss carryforwards.

We are subject to the tax laws and regulations of the State of Israel and numerous other jurisdictions in which we do business. Many judgments are required in determining our provision for income taxes and other tax liabilities, and the applicable tax authorities may not agree with our tax positions. In addition, our tax liabilities are subject to other significant risks and uncertainties, including those arising from potential changes in laws and/or regulations in the State of Israel and the other countries in which we do business, the possibility of adverse determinations with respect to the application of existing laws, changes in our business or structure and changes in the valuation of our deferred tax assets and liabilities. As of December 31, 2020, we had net operating loss carryforwards ("NOLs") for tax purposes of approximately $27.3 million. If we are unable to fully utilize our NOLs to offset taxable income generated in the future, our future cash taxes could be materially and negatively impacted. For further detail regarding our NOLs, see Note 21 in our consolidated financial statements included in this Annual Report.

It may be difficult to enforce a U.S. judgment against us and our officers and directors in Israel or the United States, or to assert U.S. securities laws claims in Israel or serve process on our officers and directors.

We are incorporated in Israel. All of our directors and executive officers and the Israeli experts named in this Annual Report reside outside the United States. The majority of our assets and the assets of these persons are located outside the United States. Therefore, it may be difficult for an investor, or any other person or entity, to enforce a U.S. court judgment based upon the civil liability provisions of the U.S. federal securities laws against us or any of these persons in a U.S. or Israeli court, or to effect service of process upon these persons in the United States. Additionally, it may be difficult for an investor, or any other person or entity, to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws on the grounds that Israel is not the most appropriate forum in which to bring such a claim. Even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact by expert witnesses, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above.

Moreover, an Israeli court will not enforce a non-Israeli judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases), if its enforcement is likely to prejudice the sovereignty or security of the State of Israel, if it was obtained by fraud or in the absence of due process, if it is at variance with another valid judgment that was given in the same matter between the same parties, or if a suit in the same matter between the same parties was pending before a court or tribunal in Israel at the time the foreign action was brought.

Your rights and responsibilities as our shareholder are governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. corporations.

Since we are incorporated under Israeli law, the rights and responsibilities of our shareholders are governed by our articles of association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders of U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to the company's articles of association, an increase of the company's authorized share capital, a merger of the company and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from discriminating against other shareholders. In addition, a controlling shareholder or a shareholder who knows that it possesses the power to determine the outcome of a shareholders vote, or who has the power to appoint or prevent the appointment of an office holder in the company or has other powers towards the company, has a duty to act in fairness towards the company. However, Israeli law does not define the substance of this duty of fairness. See "Item 6. Directors, Senior Management and Employees — Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law — Duties of Shareholders." There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on our shareholders that are not typically imposed on shareholders of U.S. corporations.

Provisions of Israeli law and our articles of association may delay, prevent or make undesirable an acquisition of all or a significant portion of our shares or assets.

Certain provisions of Israeli law and our articles of association could have the effect of delaying or preventing a change in control and may make it more difficult for a third party to acquire us or for our shareholders to elect different individuals to our board of directors, even if doing so would be beneficial to our shareholders, and may limit the price that investors may be willing to pay in the future for our ordinary shares. For example, Israeli corporate law regulates mergers and requires that a tender offer be effected when more than a specified percentage of shares in a public company are purchased. Under our articles of association, a merger shall require the approval of two-thirds of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy, and any amendment to such provision shall require the approval of 60% of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy. Further, Israeli tax considerations may make potential transactions undesirable to us or to some of our shareholders whose country of residence does not have a tax treaty with Israel granting tax relief to such shareholders from Israeli tax. With respect to certain mergers, while Israeli tax law permits tax deferral, the deferral is contingent on certain restrictions on future transactions, including with respect to dispositions of shares received as consideration, for a period of two years from the date of the merger. See Exhibit 2.1, "Description of Securities —Acquisitions Under Israeli Law," incorporated herein by reference.

Item 4. Information on the Company

Corporate Information

We were incorporated under the laws of the State of Israel on December 13, 1990 under the name Kamada Ltd. In August 2005, we successfully completed an initial public offering on the TASE. In June 2013, we successfully completed an initial public offering in the United States on Nasdaq. The address of our principal executive office is 2 Holzman St., Science Park, P.O. Box 4081, Rehovot 7670402, Israel, and our telephone number is +972 8 9406472. Our website address is www.kamada.com. The reference to our website is intended to be an inactive textual reference and the information on, or accessible through, our website is not intended to be part of this Annual Report. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding registrants like us that file electronically with the SEC. You can also inspect the Annual Report on that website.

We have irrevocably appointed Puglisi & Associates as our agent to receive service of process in any action against us in any United States federal or state court. The address of Puglisi & Associates is 850 Library Avenue, Suite 204, P.O. Box 885, Newark, Delaware 19715.

Capital Expenditures

For a discussion of our capital expenditures, see "Item 5. Operating and Financial Review and Prospects—Liquidity and Capital Resources."

Business Overview

We are a global specialty plasma-derived biopharmaceutical company with a diverse portfolio of marketed products, a robust development pipeline and industry-leading manufacturing capabilities. Our strategy is focused on driving profitable growth from our current commercial activities and our plasma-derived product development and manufacturing expertise. We operate in two segments: the Proprietary Products segment, in which we use our proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to manufacture, in our cGMP compliant, FDA-approved production facility located in Beit Kama, Israel, six plasma-derived biopharmaceutical products that we market in more than 20 countries, including our two leading products GLASSIA and KEDRAB; and the Distribution segment, in which we leverage our expertise and presence in the Israeli market by distributing more than 20 pharmaceutical products manufactured by third-parties for use in Israel.

Our core focus is on driving profitable growth from our current commercial activities and manufacturing expertise. We intend to expand our Proprietary plasma-derived products business by maximizing the market potential of our existing Proprietary products portfolio, broadening our Distribution products portfolio, enhancing our current manufacturing capabilities, and evolving into a vertically integrated plasma-derived company. We also continue to develop our pipeline, primarily focusing on the pivotal Phase 3 InnovAATe clinical trial of Inhaled AAT for the treatment of AATD and the development of our Anti-SARS-CoV-2 IgG product, and on exploring new strategic business development opportunities. Additionally, in a post-COVID-19 era, in order to address unmet medical needs in potential future emerging healthcare pandemic/epidemic crises, we also intend to leverage our expertise in plasma-derived protein therapeutics to establish a holistic IgG readiness offering and identify additional opportunities in complementary pandemic-related treatment solutions.

GLASSIA, was the first liquid, ready-to-use, intravenous plasma-derived AAT product approved by the FDA (GLASSIA is also approved for self-administration). GLASSIA is an intravenous AAT product that is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to AATD. We market GLASSIA through a strategic partnership with Takeda in the United States. Our 2020 revenues from the sale of GLASSIA to Takeda totaled $64.9 million, as compared to $68.1 million and $63.3 million during 2019 and 2018, respectively. Based on our exclusive manufacturing, supply and distribution agreement with Takeda, we project that total revenues from sales of GLASSIA to Takeda during 2021 will be approximately $25 million, which is Takeda's minimum commitment for 2021 pursuant to our existing supply agreement. Based on the licensing and technology transfer agreement between the parties, Takeda is planning to complete the technology transfer of GLASSIA, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021. Accordingly, based on the agreement between the companies, upon initiation of sales of GLASSIA manufactured by Takeda, it will pay royalties to us at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually for each of the years from 2022 to 2040. While the transition to royalties phase will result in a reduction of our revenue from Takeda, we expect, based on current GLASSIA sales in the U.S. and forecasted future growth, to receive royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040.

We also market GLASSIA in other counties through local distributors. Total revenues derived from sales of GLASSIA in all other countries during 2020 was $5.5 million, as compared to $5.5 million and $5.0 million during 2019 and 2018, respectively.

KamRAB, a hyper-immune plasma-derived therapeutic for prophylactic treatment against rabies infection administered to patients after exposure to a suspected rabid animal, is manufactured by us from plasma that contains high levels of antibodies from donors that have been previously vaccinated by an active rabies vaccine. KamRAB has been sold by us in various markets outside the United States through local distributors since 2003. In July 2011, we signed a strategic distribution and supply agreement with Kedrion for the clinical development and marketing in the United States of KamRAB, and in August 2017 we received FDA approval for anti-rabies immunoglobulin as a post-exposure prophylaxis against rabies infection. In April 2018, we launched KamRAB in the United States, under the trademark "KEDRAB." Our overall revenues from sales of KEDRAB to Kedrion during 2020, 2019 and 2018 were $18.3 million, $16.4 million and $11.8 million, respectively. Sales of KEDRAB by Kedrion in the United States during the year 2020, 2019 and 2018 totaled $23.7 million, $31.4 million and $15.5 million, respectively. Based on information provided by Kedrion, these sales represent approximately 23%, 20% and 10% share of the relevant U.S. market in each of these years, respectively. The decrease in sales of KEDRAB by Kedrion during 2020 is attributable to the COVID-19 pandemic effect and resulted in higher than planned inventory levels at Kedrion as of December 31, 2020.

In addition to GLASSIA and KEDRAB (and KamRAB), we manufacture two variations of a plasma-derived Anti-D product (intramuscular ("IM") for prophylaxis of hemolytic disease of newborns and intravenous for the treatment of immune thermobocytopunic purpura), which are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America and Asia, as well as two types of anti-snake venom derived from equine plasma, which are sold to the IMOH**.**

We intend to leverage our experience and available manufacturing capacity at our FDA-approved manufacturing facility to attempt to initiate the production of additional plasma-derived products following the transition of GLASSIA manufacturing to Takeda during 2021 through acquisitions or provision of CMO services. In line with this strategy, in December 2019, we entered into a binding term sheet for a 12-year contract manufacturing agreement with an undisclosed partner to manufacture an FDA-approved and commercialized specialty hyper-immune globulin product.

Following the completion of currently on-going technology transfer process from the current manufacturer, and pending receipt of all required FDA approvals, we expect to commence commercial manufacturing of the product in early 2023. Based on the current market sales volume of this specialty hyper-immune globulin product, we estimate that its manufacturing opportunity will add approximately $8 million to $10 million to our annual revenues, with estimated gross margin level similar to the average gross margins of our Proprietary Products segment.

During January 2021, we entered into an agreement for the acquisition, subject to customary closing conditions, of the plasma collection center of the privately-held B&PR based in Beaumont, Texas, which specializes in the collection of hyper-immune plasma used in the manufacture of Anti-D products. Plasma-derived Anti-D products is being used for prophylaxis of hemolytic disease of newborns, and for the treatment of immune thermobocytopunic purpura. B&PR's plasma collection center is one of the few FDA-licensed centers in the U.S. producing the raw materials required for these products. The acquisition of B&PR's plasma collection center shall represent our entry into the U.S. plasma collection market and further our strategic goal of becoming a fully integrated specialty plasma company. We plan to significantly expand our hyperimmune plasma collection capacity by investing in this plasma collection center in Beaumont, Texas, and leveraging its FDA license to open additional centers in the United States. We are committed to growing our hyperimmune IgG portfolio, and believe this acquisition is a significant strategic step in that direction.

Our Distribution segment is comprised of sales in Israel of pharmaceutical products manufactured by third parties. Most of the revenues generated in our Distribution segment are from plasma-derived products manufactured by European companies, and its sales represented approximately 22%, 19% and 17% of our total revenues for the years ended December 31, 2020, 2019 and 2018, respectively. Over the past several years we continued to extend our Distribution segment products portfolio to non-plasma derived products, including recently entering into agreement with Alvotech and two additional entities for the distribution in Israel of nine different biosimilar products which, subject to EMA and subsequently IMOH approvals, are expected to be launched in Israel between the years 2022 and 2025. We estimate the potential aggregate maximum revenues, achievable within several years of launch, generated by the distribution of all nine biosimilar products to be in the range of $25 million to $35 million annually.

The COVID-19 pandemic and the resulting measures implemented in response to the pandemic are adversely affecting, and is expected to continue to adversely affect, a number of our business activities (including our research and development, clinical trials, operations, supply chains, distribution systems, product development and sales activities) as well as those of our suppliers, customers, third-party payers and patients. Due to the impact of the pandemic and these measures, we have experienced, and expect to continue to experience, unpredictable reductions in demand for certain of our products. As a consequence, we have taken several actions to ensure our manufacturing plant remains operational with limited disruption to business continuity. We have increased inventory levels of raw materials through our suppliers and service providers, have taken measures to ensure international deliveries and shipments and have taken action to reduce certain costs and activities throughout our business operations. We are complying with the State of Israel mandates and recommendations with respect to our work-force management and currently maintain the work-force levels required to support our ongoing commercial operations. We have taken a number of precautionary health and safety measures to safeguard our employees and continue to monitor and assess orders issued by the State of Israel and other applicable governments to ensure compliance with evolving COVID-19 guidelines. While we initiated the development program of our Anti-SARS-CoV-2 IgG therapy for COVID-19, the COVID-19 pandemic affected some of our other research and development programs, resulting in certain delays. The outbreak and preventative or protective actions that governments, corporations, individuals or we have taken or may take in the future to contain the spread of COVID-19 may result in a period of reduced operations, reduced product demand or limit the ability of customers to perform their obligations to us, delays in clinical trials or other research and development efforts, business disruption for us and our suppliers, customers and other third parties with which we do business and potential delays or disruptions related to regulatory approvals.

A number of factors, including but not limited to, continued effect of the factors mentioned above as well as, continued demand for our products, including GLASSIA and KEDRAB in the U.S. market and our distributed products in Israel, financial conditions of our customers, suppliers and services providers, our ability to manage operating expenses, additional competition in the markets that we compete, regulatory delays, prevailing market conditions and the impact of general economic, industry or political conditions in the U.S., Israel or otherwise, may have an effect on our future financial position and results of operations.

The financial impact of these factors cannot be reasonably estimated at this time but may materially affect our business, financial condition, and results of operation. The full extent to which the pandemic impacts our business, and financial results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and duration of the pandemic and actions to contain its spread or treat its impact, among others.

The expected reduction in our GLASSIA sales to Takeda during 2021 (as mentioned above), and the higher levels of inventory of our commercial products at our distributers (including that of KEDRAB with Kedrion) as well as our Israeli customers, and the continued effect of change in product sales mix during 2021, as well as reduced plant utilization, are anticipated to result in a reduction in revenues and profitability in 2021.

In addition to our commercial operation, we invest in research and development of new product candidates and new indication for existing products activities. Our two leading investigational product candidates are Anti-SARS-CoV-2 IgG as a potential treatment for COVID-19 and Inhaled AAT for AATD. For our Anti-SARS-CoV-2 IgG, we previously reported the completion of enrollment and positive interim results from our Phase 1/2 open-label, single-arm, multi-center clinical trial. We are currently assembling the final study report and plan to publish final results before the end of the first quarter of 2021. In addition, we executed an agreement with the IMOH to supply the product for the treatment of COVID-19 patients in Israel, and recently initiated the supply of the product. The initial order is sufficient to treat approximately 500 hospitalized patients and is expected to generate approximately $3.4 million in revenue in 2021. The IMOH has initiated a multi-center clinical study through which our product is being administered. In April 2020, we entered into a binding term sheet with Kedrion for the co-development, manufacturing and distribution of our human plasma-derived Anti-SARS-CoV-2 IgG product as a potential treatment for coronavirus patients. For Inhaled AAT for AATD, we are currently conducting the InnovAATe clinical trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial.

We have also initiated development of recombinant human Alpha 1 Antitrypsin (“rhAAT”). We engaged Cellca (CDMO located in Germany, part of Sartorius Stedim BioTech Group) to pursue the cell line development of rhAAT in Chinese Hamsters Ovaries with high productivity and adequate product quality.

Our Commercial Product Portfolio

Our products include plasma-derived protein therapeutics produced in our Proprietary Products segment or licensed products, some of which are plasma-derived marketed and sold in our Distribution segment in Israel.

Proprietary Products Segment

Our products in the Proprietary Products segment consist of plasma-derived protein therapeutics derived from human serum, that are administered by injection or infusion. We also manufacture anti-snake venom products from equine based serum.

Our Proprietary Products sales accounted for approximately 76%, 77% and 79% of our total revenues for the years ended December 31, 2020, 2019 and 2018. Our leading product in the Proprietary Products segment is GLASSIA, sales of which (worldwide, including to Takeda), for the years ended December 31, 2020, 2019 and 2018, accounted for approximately 53%, 58% and 60% of our total revenues, respectively. Sales of GLASSIA to Takeda for further distribution in the U.S. market comprised approximately 49%, 54% and 56% of our total revenues for the years ended December 31, 2020, 2019 and 2018, respectively. Revenues from sales of KEDRAB to Kedrion for further distribution in the U.S. market for the years ended December 31, 2020, 2019 and 2018, accounted for approximately 14%, 13% and 10% of our total revenues, respectively. Sales of KamRAB and KamRho (D) for the years ended December 31, 2020, 2019 and 2018 accounted for the substantial balance of total revenues in the Proprietary Products segment.

The following tables lists our Proprietary Products:

Product	Indication	Active Ingredient	Geography
GLASSIA (or Ventia/Respikam in certain countries)	Intravenous AATD	Alpha-1 Antitrypsin (Human)	United States, Israel, Russia, Brazil, Argentina, Uruguay**, South Africa, Colombia**, Albania**, Kazakhstan**, Costa Rica**
KamRAB/KEDRAB	Prophylaxis of rabies disease	Anti-rabies immunoglobulin (Human)	United States, Israel, India, Thailand, El Salvador*, South Africa*, Bosnia, Russia, Mexico*, Georgia*, Sri Lanka*, Ukraine, Turkey*, South Korea, Canada, Australia and Brazil.
KamRho (D) IM	Prophylaxis of hemolytic disease of newborns	Rho(D) immunoglobulin (Human)	Israel, Brazil, India, Argentina, Paraguay, Chile, Russia, Nigeria*, Sri Lanka*, Thailand*, Costa Rica** and the Palestinian Authority
KamRho (D) IV	Treatment of immune thermobocytopunic purpura	Rho(D) immunoglobulin (Human)	Israel, India* and Argentina*
Snake bite antiserum	Treatment of snake bites by the Vipera palaestinae and the Echis coloratus	Anti-snake venom	Israel

* We have regulatory approval, but did not market the product in this country in 2020.

** Product was registered, but we have not yet started sales.

GLASSIA

GLASSIA is an intravenous AAT product produced from fraction IV plasma that is indicated by the FDA for chronic augmentation and maintenance therapy in adults with emphysema due to congenital AATD. AAT is a naturally occurring protein found in a derivative of plasma known as fraction IV. AAT regulates the activity of certain white blood cells known as neutrophils and reduces cell inflammation. Patients with genetic AATD suffer from a chronic inflammatory state, lung tissue damage and a decrease in lung function. While GLASSIA does not cure AATD, it supplements the patient's insufficient physiological levels of AAT and is administered as a chronic treatment. As such, the patient must take GLASSIA indefinitely over the course of his or her life in order to maintain the benefits provided by it. GLASSIA is administered through single weekly intravenous infusions

In the United States and Europe, we believe that AATD is currently significantly under-diagnosed and under-treated. Based on information published by the Alpha-1 Foundation, there are approximately 100,000 people with AATD in the United States and about the same number in Europe, and we estimate, based on medical literature, that only approximately 10% of all potential cases of AATD are treated. According to the Centers for Medicare and Medicaid Services published payment allowance limits for Medicare part B, the average sale price, as of January 2021, of 10 mg of GLASSIA is $4.877, resulting in an annual cost of between $80,000 and $120,000 per AATD patient. In the United States, in some of the European countries and in Israel, we believe that the majority of the cost of treatment is covered by medical insurance programs.

We estimate that the potential world market for AAT products is significantly larger than current consumption indicates. We believe that the primary reasons for this are the non-availability of AAT products in many countries, under diagnosis of patients suffering from AATD, expensive and protracted registration processes required to commence sales of AAT products in new markets and the absence of insurance reimbursement in various countries. As AATD can be diagnosed with a simple blood test, we expect diagnosis of AATD to continue to increase going forward as awareness of AAT increases. Based on a recent market analysis report, the estimated annual rate of increase of the market size in the U.S. and the five largest European countries of currently approved AATD therapies is approximately 6-8%.

GLASSIA was the first approved liquid AAT, which is ready for infusion and does not require reconstitution and mixing before injection, as is required from most other competing products. Additionally, in June 2016, the FDA approved an expanded label of GLASSIA for self-infusion at home after appropriate training. GLASSIA has a number of advantages over other intravenous AAT products, including the reduction of the risk of contamination during the preparation and infection during the infusion, reduced potential for allergic reactions due to the absence of stabilizing agents, simple and easy use by the patient or nurse, and the possible reduction of the nurse's time during home visits, in the clinic or in the hospital and the ability to self- infusion at home.

Currently, GLASSIA has been registered in ten countries, and is sold in five of those countries and also is sold in one additional country on a non-registered named-patient basis. The majority of sales of GLASSIA are in the United States, where GLASSIA was approved by the FDA in July 2010 and sales began in September 2010. As part of the approval, the FDA requested that we conduct post-approval Phase 4 clinical trials, as is common in the pharmaceutical industry, aimed at collecting additional safety and efficacy data for GLASSIA. Pursuant to our agreement with Takeda (See "— Strategic Partnerships — Takeda."), the Phase 4 clinical trials are financed and managed by Takeda, provided that if the cost of such Phase 4 clinical trials exceeds a pre-defined amount, we will participate in financing such trial up to a certain amount by offsetting such amounts from future milestones, sales of GLASSIA or royalties from Takeda. The first Phase 4 safety study completed enrollment of a total of 30 subject in the U.S. and Canada during 2020 and its results are currently being analyzed. The second Phase 4 efficacy study was initiated during 2016 and was terminated two years after initiation based on DSMB's recommendation due to very low recruitment rates. During 2019, Takeda submitted a revised Phase 4 protocol to the FDA, which is currently still under review and discussion with the agency. There have subsequently been several interactions with the FDA with respect to the Phase 4 efficacy study requirement, and Takeda is currently evaluating how to proceed in view of the FDA requirements and cumulative clinical data collected to date on AATD augmentation treatment.

We market GLASSIA in the United States through our partnership with Takeda. We market GLASSIA in Israel by ourselves and in other countries through local distributors. Sales to Takeda accounted for approximately 49%, 54% and 56% of our total revenues in the years ended December 31, 2020, 2019 and 2018, respectively. We submitted and plan to submit GLASSIA for marketing approval in additional countries. Our revenues from sales of GLASSIA worldwide have grown from approximately $0.6 million in 2009 to $70.3 million in 2020, representing 49% compound annual growth rate.

Based on our exclusive manufacturing, supply and distribution agreement with Takeda, we project that total revenues from sales of GLASSIA to Takeda during 2021 will be approximately $25 million, as compared to $64.9 during 2020. Based on the licensing and technology transfer agreement between the parties, Takeda is planning to complete the technology transfer of GLASSIA, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021. Accordingly, based on the agreement between the companies, upon initiation of sales of GLASSIA manufactured by Takeda, it will pay royalties to us at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually for each of the years from 2022 to 2040. While the transition to royalties phase will result in a reduction of our revenue from Takeda, we project, based on current GLASSIA sales in the U.S. and forecasted future growth, to receive royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040.

KamRAB/KEDRAB

KamRAB is a prophylactic treatment against rabies infection that is administered to patients after exposure to an animal suspected of being infected with rabies. KamRAB is a protein therapeutic derived from hyper-immune plasma, which is plasma that contains high levels of antibodies from donors that have been previously vaccinated by an active rabies vaccine. KamRAB is administered by a one-time injection, and the precise dosage is a function of the patient's weight.

According to the World Health Organization, each year, more than 10 million people worldwide are exposed to potential rabies infection. We believe that there are market opportunities for KamRAB in developing countries, as well as other countries including Canada and Australia. In many developing countries, patients do not receive treatment for suspected rabies due to the lack of availability of healthcare resources.

We began selling KamRAB in certain countries in Asia and Latin America in 2003, and currently sell KamRAB in 11 countries.

In July 2011, we signed a strategic distribution and supply agreement with Kedrion for the clinical development and marketing in the United States of KamRAB, pursuant to which Kedrion agreed to bear all the costs required for the Phase 2/3 clinical trials. See "— Strategic Partnerships — Kedrion." The results of a Phase 2/3 study demonstrated that KamRAB was non-inferior to the comparator HRIG product in achieving Rabies Virus Neutralizing Antibody (RVNA) levels of ≥0.5 IU/mL on day 14, when each was co-administered with a rabies vaccine. In addition, KamRAB was found to be well-tolerated with a safety profile similar to that of the comparator HRIG product. Based on these results, in August 2017, we received FDA approval for the marketing of KamRAB in the United States (under the trademark "KEDRAB") for post-exposure prophylaxis (PEP) against rabies infection, and in April 2018 KEDRAB was launched in the United States.

In addition, we recently completed an FDA-required post-marketing trial in the U.S. with the primary objective of confirming the safety of KEDRAB in children aged 0 to 17 years. The KEDRAB U.S. pediatric trial was conducted at two sites, one in Arkansas and another in Rhode Island. The study included 30 pediatric patients (ages 0-17 years old), each of whom received KEDRAB as part of PEP treatment following exposure or suspected exposure to an animal suspected or confirmed to be rabid, and safety follow-up was conducted for up to 84 days. The primary objective of the study was to confirm the safety of KEDRAB in the pediatric population. Secondary objectives included the evaluation of antibody levels and the effectiveness of KEDRAB in the prevention of rabies disease when administered with a rabies vaccine according to the PEP recommended guidelines. No serious adverse events were observed during the study. No incidence of rabies disease or deaths were recorded throughout the 84-day study period. The results have been submitted to the FDA for review and inclusion as pediatric data in the KEDRAB full prescribing information.

We believe that FDA approval for marketing the product will assist us in our efforts to register and market KamRAB in additional countries, which we believe would lead to additional sales worldwide. In November 2018, we received marketing approval for KamRAB in Canada and following winning a recent supply tender, we started selling the product in Canada during 2020. We were also recently approved to supply KamRAB through the PAHO, the specialized international health agency for the Americas. We initiated sales of KamRAB through PAHO during 2019.

KamRho (D)

KamRho (D) is indicated for (i) the prevention of hemolytic disease of the newborn ("HDN"), which is a blood disease that occurs where the blood type of the mother is incompatible with the blood type of the fetus; and (ii) a second line treatment of immune thrombocytopenic purpura ("ITP"), which is thought to be an autoimmune blood disease in which the immune system destroys the blood's platelets, which are necessary for normal blood clotting. KamRho (D) is produced from hyper-immune plasma and is administered through intra-muscular injection (KamRho (D) IM) or through intravenous infusion (KamRho (D) IV).

According to academic research, approximately 15% of Caucasian women are Rh-negative and, if left untreated, HDN would affect one percent of all newborns and would be responsible for the death of one baby out of every 2,200 births. In addition, academic research estimates that ITP affects approximately five out of every 100,000 children per year, and two of every 100,000 adults per year worldwide, although some will recover without treatment. We have completed the registration process for Kam Rho (D) in several countries and sell it in eight countries, including Israel, Latin America, Asia, Africa and Eastern Europe.

Snake Bite Antiserum

Our snake bite antiserum product is used for the treatment of humans that have been bitten by the most common Israeli viper (*Vipera palaestinae)* and by the Israeli Echis *(Echis coloratus).* The venom of these snakes is poisonous and causes, among other symptoms, severe immediate pain with rapid swelling. These snake bites can lead to death if left untreated. Our snake bite antiserum is produced from hyper-immune serum that has been derived from horses that were immunized against Israeli viper and Israeli Echis venom. This product is the only treatment on the market for *Vipera palaestinae* and *Echis coloratus* snake bites in Israel.

We manufacture the snake bite antiserum pursuant to an agreement with the IMOH entered into in March 2009. We completed construction of the production facilities and laboratories for the product, and successfully passed the IMOH inspections. We began production of our snake bite antiserum in August 2011 and commenced sales to the IMOH in 2012. The agreement with the IMOH expired on December 31, 2020 and we are in the process of negotiating a renewal to the agreement.

Distribution Segment

Our Distribution segment is comprised of sales in Israel of pharmaceutical products manufactured by third parties. We engage third party manufacturers, register their products with the IMOH, import the products to Israel and distribute them to local HMOs, hospitals and pharmacists. Our Distribution segment sales accounted for approximately 24%, 23% and 21% of our total revenues for the years ended December 31, 2020, 2019 and 2018, respectively. Our primary products in the Distribution segment include pharmaceuticals for critical use delivered by injection, infusion or inhalation. Currently, most of the revenues generated in our Distribution segment are from products produced from plasma or plasma-derivatives, and are manufactured by European companies. IVIG is our primary product in the Distribution segment, comprising approximately 76%, 62% and 58% of total revenues in the Distribution segment for the years ended December 31, 2020, 2019 and 2018, respectively. Sales of IVIG accounted for approximately 19%, 14% and 12% of our total revenues for the years ended December 31, 2020, 2019 and 2018, respectively.

Over the past several years we continued to extend our Distribution segment products portfolio to non-plasma derived products and in December 2019, we entered into an agreement with Alvotech, a global biopharmaceutical company, to commercialize Alvotech's portfolio of six biosimilar product candidates in Israel, upon receipt of regulatory approval from the IMOH. Alvotech's pipeline includes biosimilar product candidates aimed at treating autoimmunity, oncology and inflammatory conditions. Subject to approval by the IMOH, we expect to launch the first of these products, Bonsity, in Israel during 2022. Bonsity is a biosimilar candidate to teriparatide, an FDA approved product marketed by Eli Lilly and Company under the brand name Forteo®/Forsteo® for the treatment of osteoporosis in patients with a high risk of fracture. Bonsity recently received FDA approval. Following receipt of EMA marketing approval by Alvotech, the remaining five products included in the agreement are, subject to approval by the IMOH, expected to be launched in Israel during the years 2023-2025. The Israeli market for the approved reference products to which Alvotech's six biosimilar products are targeted is estimated to be in the range of $125 million to $150 million for 2018. Based on the projected list price reduction due to increased competition as a result of the launch of these six biosimilar products, and anticipated market penetration potential, we estimate the potential aggregate maximum revenues from the sale of all six products, achievable within several years of launch, generated by the distribution of all six biosimilar products to be in the range of $20 million to $30 million annually.

In addition, in January 2021, we announced the entering into agreements with two undisclosed international pharmaceutical companies to commercialize three biosimilar product candidates in Israel. Subject to approval by the EMA and subsequently by the IMOH, the three products are expected to be launched in Israel between 2022 and 2024. The two pharmaceutical companies will maintain development, manufacturing and supply responsibilities for these three products. The Israeli market for the referenced innovative products to which these three biosimilar products are targeted was between approximately $20 million to $25 million in 2019, and we estimate the potential collective maximum sales generated by the distribution of these three products, achievable following regulatory approval and within several years of launch, to be in the range of $5 million to $7 million annually.

The following table sets forth our primary products in our Distribution segment.

Product	Indication	Active Ingredient
Respiratory		
Bramitob	Management of chronic pulmonary infection due to pseudomonas aeruginosa in patients six years and older with cystic fibrosis	Tobramycin
FOSTER	Regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate	Beclomethasone dipropionate, Formoterol fumarate
PROVOCHOLINE	Diagnosis of bronchial airway hyperactivity in subjects who do not have clinically apparent asthma	Methacholine Chloride
AeroBika	*OPEP device*	None
Immunoglobulins		
IVIG 5%	Treatment of various immunodeficiency-related conditions	Gamma globulins (IgG) (human)
Varitect	Preventive treatment after exposure to the virus that causes chicken pox and zoster herpes	Varicella zoster immunoglobulin (human)
Zutectra	Prevention of hepatitis B virus (HBV) re-infection in HBV-DNA negative patients 6 months after liver transplantation for hepatitis B induced liver failure	Human hepatitis B immunoglobulin
Hepatect CP	Prevent contraction of Hepatitis B by adults and children older than two years	Hepatitis B immunoglobulin (human)
Megalotect	Contains antibodies that neutralize cytomegalovirus viruses and prevent their spread in immunologically impaired patients	CMV immunoglobulin (human)
RUCONEST	Treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency	Conestat Alfa
Critical Care		
Heparin sodium injection	Treatment of thrombo-embolic disorders such as deep vein thrombosis, acute arterial embolism or thrombosis, thrombophlebitis, pulmonary embolism, fat embolism. Prophylaxis of deep vein thrombosis and thromboembolic events	Heparin sodium
Albumin and Albumin 4%	Maintains a proper level in the patient's blood plasma	Human serum Albumin
Coagulation Factors		
Factor VIII	Treatment of Hemophilia Type A diseases	Coagulation Factor VIII (human)
Factor IX	Treatment of Hemophilia Type B disease	Coagulation Factor IX (human)
Vaccinations		
IXIARO	Active immunization against Japanese encephalitis in adults, adolescents, children and infants aged 2 months and older	Japanese encephalitis purified inactivated vaccine
Metabolic Disease		
Procysbi	nephropathic cystinosis in adults and children 1 year of age and older	Cysteamine Biartrate

Contract Manufacturing Services

In preparation for the transition of GLASSIA manufacturing to Takeda, expected by 2021, and in accordance with our business development strategy focused on creating new growth opportunities through identification of new product opportunities for our manufacturing plant, we are proactively exploring opportunities to leverage our experience and manufacturing capacity to initiate the production of new plasma-derived products. As such, in December 2019, we entered into a binding term sheet for a 12-year contract manufacturing agreement with an undisclosed partner to manufacture an FDA-approved and commercialized specialty hyper-immune globulin product. Following the execution of the required technology transfer from the current manufacturer, and pending receipt of all required FDA approvals, we expect to commence commercial manufacturing of the product in early 2023. Based on the current market sales volume of this specialty hyper-immune globulin product, we estimate that its manufacturing will add approximately $8 million to $10 million to our annual revenues, with estimated gross margin level similar to the average gross margins of our Proprietary Products segment.

Our Development Product Pipeline

Our research and development activities include conducting pre-clinical and clinical trials and other development activities for our pipeline products, improving existing products and processes, development work at the request of regulatory authorities and strategic partners, as well as communication with regulatory authorities related to our commercial products as well as clinical programs. We incurred approximately $13.6 million, $13.1 million, and $9.7 million in research and development expenses in the years ended December 31, 2020, 2019 and 2018, respectively.

We are in various stages of pre-clinical and clinical development of new product candidates for our Proprietary Products segment. The following table sets forth our primary product pipeline in our Proprietary Products segment and each such product's stage of development:

Product	Indication	Phase 1 Phase 2 Phase 3	Other Information
Clinical Development			
Hyperimmune IgG	COVID-19	Phase 1/2 (initiated - IL) ------→	Global collaboration KEDRION
Inhaled AAT	AAT Deficiency[1]	Phase 2/3 EU (completed)[2] ----------→ Phase 2 US (completed) ----------→ Phase 3 unified EU&US ----------→ (FPI in EU in 12/2019)	May seek commercialization partnering
Early-Stage Development			
Liquid AAT	Organ preservation	Early development	
Recombinant AAT	TBD	Early development	

1. *Orphan drug designation (US & EU);*
2. *Study failed to meet primary end-point &MAA withdrawn (6-2017);*

Anti-SARS-CoV-2 IgG Product as a Potential Treatment for COVID-19

In response to the recent COVID-19 outbreak, in early 2020 we initiated the development of a human plasma-derived Anti-SARS-CoV-2 polyclonal immunoglobulin (IgG) product using our proprietary plasma derived IgG platform technology as a potential treatment for COVID-19. The development of our investigational Anti-SARS-CoV-2 IgG product is done with full cooperation with IMOH. The product is developed in line with the requirement of Ph Eur for IV Ig product and based on our established technology platform for IgG, as approved in the United States, Israel and other international markets.

During April 2020, we announced a global collaboration with Kedrion for the development, manufacturing and distribution of our Anti-SARS-CoV-2 IgG product as a potential treatment for COVID-19 patients. Pursuant to the agreed terms, Kedrion will provide plasma, collected at its KEDPLASMA centers, from donors who have recovered from the virus and, upon receipt of regulatory approvals, will be responsible for commercialization of the product in the U.S., Europe, Australia, and South Korea, United Kingdom, Switzerland and Norway. We are responsible for product development, manufacturing, clinical development, with Kedrion's support, and regulatory submissions. We will also assume distribution responsibility in all territories outside of those Kedrion is responsible for. Marketing rights for the product in China will be shared by the parties. Kedrion is currently collecting COVID-19 convalescent plasma from U.S. recovered patients that will be used by us to manufacture batches of the product. Kedrion is collecting the plasma, through its plasma business unit, KEDPLASMA, at 26 FDA-approved centers across the United States.

In June 2020, our Anti-SARS-CoV-2 IgG product became available for compassionate use treatment in Israel, and In August 2020, we initiated a Phase 1/2 open-label, single-arm, multi-center clinical trial in Israel of our Anti-SARS-CoV-2 IgG product. We completed enrollment in September 2020 and announced initial interim results for the Phase 1/2 clinical trial. A total of 12 eligible patients (age 34-69) were enrolled in the trial and received our product at a single dose of 4 grams IgG within five to 10 days of initial symptoms. Patient follow-up occurs for 84 days. To date, symptoms improvement was observed in 11 of the 12 patients within 24 to 48 hours from treatment. All 11 patients were subsequently discharged from the hospital within a median hospital stay of 4.5 days from treatment. The medical condition of one patient, continue to deteriorate and after few weeks on mechanical ventilation he died. One patient had a serious adverse event four days after treatment, which was categorized by the investigator as unrelated to our IgG product that the patient received in the trial. All 11 patients completed the 84 days follow-up with no relapse or additional SAEs. We expect the final trial results to be available during the first quarter of 2021.

In August 2020, the FDA issued an Emergency Use Authorization for convalescent plasma as a potential treatment for COVID–19. Convalescent plasma plays an important role in the immediate and intermediate response to the disease. Plasma-derived IgG product, as developed by us, is considered to have multiple advantages over convalescent plasma transfusion, such as standardized antibody levels, higher potency, extensive viral inactivation processing, the absence of a blood-type matching requirement, smaller infusion volumes, the ability to be produced in large quantities, and preferred storage conditions.

To potentially expand our COVID-19 clinical development program to the U.S., we, with the support of Kedrion, submitted a pre-Investigational New Drug ("IND") information package to the FDA with our proposed U.S. clinical development plan. Following the FDA's response to our pre-IND information package, we, together with Kedrion, continue to evaluate the best suitable plan for the U.S. and/or EU COVID-19 IgG clinical program, and will advance our development upon the conclusion of this review.

In October 2020, we signed an agreement with the IMOH to supply our investigational Anti-SARS-CoV-2 IgG product for the treatment of COVID-19 patients in Israel. We manufacture the product, to be supplied to the IMOH, from convalescent plasma collected and supplied by the Israeli National Blood Services, a division of Magen David Adom (MADA), as well as plasma collected by Kedrion. The initial order, planned to be supplied during the first few months of 2021, is sufficient to treat approximately 500 hospitalized patients. This initial supply is expected to generate approximately $3.4 million in revenue in 2021. The IMOH has initiated a multi-center clinical study through which our product is being administered.

From a supply perspective, we are ramping up our COVID-19 IgG manufacturing capacity, and we intend to increase our supply capabilities during 2021 to support potential additional demand from the Israeli MOH, and possibly other international markets.

Inhaled Formulations of AAT for AATD

We are in the process of development of inhaled formulations of AAT administered through the use of a nebulizer. The nebulizer was developed by PARI. Inhaled AAT for AATD has been designated as an orphan drug for the treatment of AATD in the United States and Europe.

We have been able to leverage our expertise gained from the production of GLASSIA to develop a stable, high-purity Inhaled AAT for AATD, an inhaled AAT product candidate for the treatment of AATD. Existing treatment for AATD require weekly intravenous infusions of AAT therapeutics. We believe that Inhaled AAT for AATD, if approved, will significantly improve the patient's disease condition and the quality of life of the patients versus current invasive weekly treatment that requires uncomfortable infusion, consumption of time and administration by a medical professional. If approved, Inhaled AAT for AATD is estimated to be the first AAT product that is not required to be delivered intravenously and instead is administered by a user-friendly, lightweight and silent nebulizer in up to two short daily sessions. We believe that Inhaled AAT for AATD, if approved, will increase patient convenience and reduce or replace the need for patients to use intravenous infusions of AAT products, decreasing the need for clinic visits or nurse home visits and reducing medical costs. Because of the smaller amount of AAT product used in Inhaled AAT for AATD (since it is applied directly to the site of action rather than administered systematically) we believe that this product, if approved, will enable us to treat significantly more patients from the same amount of plasma and production capacity and may be more cost effective for patients and payors and may increase our profitability.

The current standard care for AATD in the United States and in certain European countries is a weekly intravenous infusion of an AAT therapeutic. We estimate that only 2% of the AAT dose reaches the lung when administered intravenously. We have conducted a U.S. Phase 2 clinical study demonstrating that administration of inhaled formulations of AAT through inhalation results in greater dispersion of AAT to the target lung tissue, including the lower lobes and lung periphery. Accordingly, we believe that an inhaled formulation of AAT would require a significantly lower therapeutic dose and would be more effective in reducing inflammation of the lung tissue and inhibiting the uncontrolled neutrophil elastase that causes the breakdown of the lung tissue and the emphysema.

We conducted a double blind placebo controlled and randomized Phase 2/3 pivotal trial, under EMA guidance, which was completed at the end of 2013. A total of 168 patients participated in the trial in seven countries in Europe and Canada. Subjects in this trial were administered with a daily dose of Inhaled AAT or equivalent dose of placebo for 50 consecutive weeks. The primary endpoint for the trial was the time from randomization to the first event-based exacerbation with a severity of moderate or severe. Other endpoints, which were secondary and tertiary, included other exacerbation measures, lung function, CT scan and quality of life. The trial was 80% powered based on the number of exacerbation events collected in the study, in order to detect a difference between the two groups one year later. A 20% difference between the two groups was required to prove efficacy and was considered clinically meaningful and would allow the decision to prescribe treatment. An open label extension of an additional 50 weeks on active drug was offered to study participants in most sites once they completed the initial 50-week period. Treatment in the open label extension of the trial was completed in November 2014.

This study did not meet its primary and secondary endpoints. However, lung function parameters, including Forced Expiratory Volume in One Second ("FEV1") % of Slow Vital Capacity ("SVC") and FEV1 % predicted, FEV1 (liters) collected to support safety endpoints, showed concordance of a potential treatment effect in the reduction of the inflammatory injury to the lung that is known to be associated with a reduced loss of respiratory function.

In accordance with guidance received following the meeting with the European rapporteur and co-rapporteur, we performed several post hoc analyses. Results of the post hoc analyses indicate that after one year of daily inhalation of our Inhaled AAT, clinically and statistically significant improvements were seen in spirometric measures of lung function, particularly in bronchial airflow measurements FEV1 (L), FEV1% predicted and FEV1/SVC. These favorable results were even more evident when analyzing the overall treatment effect throughout the full year.

For lung function, overall one year effect:

- FEV1 (L) rose significantly in AAT treated patients and decreased in placebo treated patients (+15ml for AAT vs. -27ml for placebo, a 42 ml difference, p=0.0268)
- There was a trend towards better FEV1% predicted (0.54% for AAT vs. -0.62% for placebo, a 1.16% difference, p=0.065)
- FEV1/SVC% rose significantly in AAT treated patients and decreased in placebo treated patients (0.62% for AAT vs. -0.87% for placebo, a 1.49% difference, p=0.0074)

For lung function change at week 50 vs. baseline:

- There was a trend towards reduced FEV1 (L)decline (-12ml for AAT vs. -62ml for placebo, a 50 ml difference, p=0.0956)
- There was a trend towards a reduced decline in FEV1% predicted (-0.1323% for AAT vs. -1.6205% for placebo, a 1.4882% difference, p=0.1032)
- FEV1/SVC% rose significantly in AAT treated patients and decreased in placebo treated patients (0.61% for AAT vs. -1.07% for placebo, a 1.68% difference, p=0.013)

During March 2014, we initiated Phase 2 trials in the United States. The trial was completed in May 2016. This trial was intended to serve as a supplementary trial to the European Phase 2/3 trial and was designed to incorporate parameters required by the FDA. This Phase 2, double-blind, placebo-controlled study explored the ELF and plasma concentration as well as safety of Inhaled AAT in AATD subjects. The subjects received one of two doses of Inhaled AAT or placebo. The study involved the inhalation of 80 mg or 160 mg of human AAT or placebo twice daily via the eFlow device for 12 weeks. Following the 12 week double blind period, the subjects were offered to participate in an additional 12 weeks open label period during which they receive only Inhaled AAT therapy. In December 2015, we completed the enrollment of patients for the U.S. Phase 2 clinical trial, and in August 2016, we reported positive top-line results, according to which we met the primary endpoint.

AATD patients treated with our Inhaled AAT product in such U.S. Phase 2 clinical trial, demonstrated a significant increase in endothelial lining fluid (“ELF”) AAT antigenic level compared to the placebo group [median increase 4551 nM, p-value<0.0005 (80 mg/day, n=12), and 13454 nM, p-value<0.002 (160mg/day, n=12)]. These results are more than twice the increase of ELF antigenic AAT level (+2600 nM) observed in our previously completed intravenous AAT pivotal study (60mg/kg/week). Antigenic AAT represents the total amount of AAT in the lung, both active and inactive. The study results also showed that our Inhaled AAT is more efficient than IV to restore ELF AAT level within the lung. In addition, ELF Anti-Neutrophil Elastase inhibitory (“ANEC”) level also increased significantly [median increase 2766 nM, p-value<0.0005 (80mg/day) and 3557 nM., p-value<0.004 (160 mg/day)]. The increase in ELF ANEC level was also more than twice that demonstrated in our previously completed IV AAT pivotal study. The ANEC level represents the active AAT that can counterbalance further damage by neutrophil elastase.

The updated data included in our poster presentation of May 2017 demonstrated that ELF-AAT, neutrophil elastase (NE)-AAT and ANEC complexes concentration significantly increased in subjects receiving the 80 mg and 160 mg doses, (median increase of 38.7 neutrophil migration (nM), p-value<0.0005 (80 mg/day, n=12), and median increase of 46.2 nM, p-value<0.002 (160 mg/day, n=10)). This is a specific measure of the anti-proteolytic effect in the ELF and represents the amount of NE that was broken down by AAT. The increase in levels of functional AAT was six times higher (160 mg per day) than is achievable with intravenous (IV) AAT. In addition, ELF NE decreased significantly. Also, the 80 mg data demonstrated a significant reduction in the percentage of neutrophils. Finally, aerosolized M-specific AAT was detected in the plasma of all subjects receiving Inhaled AAT, consistent with what was seen in the Phase 2/3 clinical trial of our Inhaled AAT conducted in the EU.

We filed the MAA for our Inhaled AAT for AATD during the first quarter of 2016 and in June 2017 we withdrew the MAA, as following extensive discussions with the EMA, we concluded that the EMA did not view the data submitted as sufficient, in terms of safety and efficacy, for approval of the MAA, and that the supplementary data needed for approval required an additional clinical trial. While the post-hoc data provided by us from the European clinical trial showed a statistically significant and clinically meaningful improvement in lung function, the EMA was of the opinion that an overall positive conclusion on the effect of Inhaled AAT for AATD could not be reached based on that post-hoc analysis, and that the treatment of AATD patients with our Inhaled AAT product should be further evaluated in the clinic in order to obtain comprehensive long-term efficacy and safety data. The EMA was of the opinion that the study failed to show beneficial effects in the population studied. In addition, there were concerns about the tolerability and safety profile of the AAT, mainly in patients with severe lung disease. In addition, the EMA raised concerns about the high rate of patients with antibodies (ADA) responding to AAT, which might reduce its effects or make patients more prone to allergic reactions, despite evidence that none of the patients with such ADA response had allergic reaction nor a lower level of AAT in the serum.

When we presented the data from the European Phase 2/3 study to the FDA, the agency expressed concerns and questions about that data, primarily related to the safety and efficacy of Inhaled AAT for the treatment of AATD and the risk/benefit balance to patients based on that data and product characteristics. Following several discussions with the FDA and EMA, through which we provided both agencies additional data and information in response to their concerns and questions and addressed both agencies' guidance with respect to our proposed subsequent phase 3 pivotal study protocol, we received positive scientific advice from the CHMP of the EMA related to the development plan for our proposed pivotal Phase 3 pivotal study for Inhaled AAT for AATD, and in April 2019, we received a letter from the FDA stating that we had satisfactorily addressed the concerns and questions with respect to the proposed Phase 3 clinical trial.

During December 2019, we announced that the first patient was randomized in Europe into our pivotal Phase 3 InnovAATe clinical trial evaluating the safety and efficacy of our proprietary inhaled AAT therapy for the treatment of AATD. The study is being led by Jan Stolk, M.D., Department of Pulmonology, Member of European Reference Network LUNG, Leiden University Medical Center, The Netherlands. InnovAATe is a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial designed to assess the efficacy and safety of Inhaled AAT in patients with AATD and moderate lung disease. Up to 250 patients will be randomized 1:1 to receive either Inhaled AAT at a dose of 80mg once daily, or placebo, over two years of treatment. The primary endpoint of the InnovAATe trial is lung function measured by FEV1. Secondary endpoints include lung density changes as measured by CT densitometry, as well as other parameters of disease severity, such as additional pulmonary functions, exacerbation rate and six-minute walk test. The safety profile will be monitored continuously by a Data Monitoring Committee with predefined rules to be applied after the first 60 subjects have completed six months of treatment.

Enrolment in the pivotal Phase 3 InnovAATe clinical trial, which continued through February 2020, was temporarily halted due to the impact of COVID-19 pandemic on healthcare systems. Patients already recruited to the study continued treatment as planned. Enrollment into the study was resumed in the third quarter of 2020, per appropriate conditions at clinical trial sites. Although we recently resumed recruitment to the study, the COVID-19 pandemic has slowed down the rate of recruitment and the current pandemic situation mainly across Europe affects our ability to currently open new study sites.

Prior to the initiation of the pivotal Phase 3 InnovAATe clinical trial we completed a Human Factor Study (HFS) to support the combination product, consisting of our Inhaled AAT and the investigational eFlow nebulizer system of PARI Pharma GmbH. Based on feedback received from the FDA, we are initiating a subsequent HFS to support improved use regimen of the product.

In addition to the pivotal study and based on feedback received from the FDA regarding anti-drug antibodies (ADA) to Inhaled AAT, we intend to concurrently conduct a sub-study in North America in which approximately 30 patients will be evaluated for the effect of ADA on AAT levels in plasma with Inhaled AAT and IV AAT treatments. We already obtained FDA acceptance of the protocol design for the study; however, initiation of this sub-study has been delayed due to the effect of the COVID-19 pandemic.

From a strategic standpoint, we continue to evaluate partnering opportunities for the development and commercialization of this important pipeline product.

Liquid AAT for Organ Preservation Prior to Transplantation

AAT has been found to have anti-inflammatory, tissue-protective, immune-modulatory and anti-apoptotic properties. These characteristics may decrease tissue injury by lowering levels of pro-inflammatory cytokines and proteases associated with organ injury during harvest and transplantation, the prevalent causes of organ transplant rejection. Organ preservation methods pre-transplantation are continuously improving due to advanced technologies, such as ex-vivo perfusion systems.

We collaborated with Massachusetts General Hospital ("MGH") in an investigator initiated, proof-of-concept study evaluating the potential benefit of AAT on liver preservation and transplant rejection prevention led by James F. Markmann, M.D., Ph.D., Chief, Division of Transplant Surgery, MGH, who is the Claude E. Welch Professor of Surgery at Harvard Medical School. The purpose of the study was to assess the effect of AAT on liver graft quality and viability and to evaluate the liver graft for markers of Ischemia-Reperfusion Injury (IRI) and tissue damage. In the first cohort of the study, organ viability parameters (e.g., liver function tests and hemodynamics, which represent risks for failure or dysfunction after transplantation), inflammatory pathway analysis and histology, were all measured and yielded positive trends. The second cohort of the study aimed to assess the effect of AAT with a different dosing. The study evaluated the effect of AAT on a liver graft once administered into an ex-vivo perfusion system.

In addition, we are currently investigating the effect of Alpha-1 antitrypsin delivered via different preservation methods on ischemia-reperfusion injury in pig kidneys. This preclinical work is being performed in collaboration with the University of Oxford at the laboratory of Prof. Ploeg, Professor of Transplant Biology; Director of Clinical and Translational Research of University of Oxford.

Recombinant AAT

We have initiated development recombinant human Alpha 1 Antitrypsin ("rhAAT"). To ensure the success of this project, we have previously developed analytical tools (physicochemical, biochemical, in-vitro, and in-vivo) that will support the selection and characterization of functional rhAAT. In addition, we have established a significant understanding on several expression systems and finally selected Cellca (CDMO located in Germany, part of Sartorius Stedim BioTech Group) to pursue the cell line development of the rhAAT in Chinese Hamsters Ovaries with high productivity and adequate product quality.

With respect to the development of our rhAAT and organ preservation, our continued investment would be subject, among other things, to attracting strategic partner(s) to collaborate in the further development of those programs.

Other Prior Research Activities

We previously tested our liquid, intravenous plasma-derived AAT product for other indications utilizing AATs known therapeutic roles given its immunomodulatory, anti-inflammatory, tissue-protective and antimicrobial properties:

- Acute Graft versus Host Disease (aGvHD) - In November 2016, we initiated a Phase 2/3 clinical trial for the treatment of aGvHD in collaboration with Shire (now part of Takeda) in the United States. In June 2017, Shire informed us of its decision not to continue with the study. As the result of this decision, the study was halted. In January 2018, we announced a collaboration with a consortium of prominent hospitals led by Mount Sinai Hospital and initiated an investigator initiated Phase 2 clinical study to evaluate our AAT product for preemption of steroid refractory aGvHD (SR-aGvHD) utilizing a novel blood biomarker developed algorithm that may identify patients at high risk of developing SR-aGvHD and non-relapse mortality. The study included 30 patients and the primary endpoint was the incidence of steroid-refractory GVHD by day 100 after transplantation. The results of the study show that treatment with IV-AAT was well-tolerated by the patients and six cases of steroid-refractory GVHD were observed. This rate of disease incidence was within the pre-determined range, defined by the investigators, that if achieved, would warrant further clinical evaluation of the treatment.

- Lung Transplantation Rejection - We have also initiated a Phase 2 clinical study with our intravenous AAT product to prevent lung transplantation rejection. In January 2018, we announced interim results from this study, which showed that our intravenous AAT demonstrated favorable safety and tolerability profile in 10 patients during first six months of treatment, consistent with previously observed results in other indications. In February 2019, we announced additional interim results from such study suggesting improvement in multiple key clinical outcomes and overall demonstrated a trend towards improvement in multiple clinical outcomes.

While we are encouraged with the results of our IV AAT in both the GvHD and lung transplantation studies, we do not intend to further advance these programs at this time, mainly as a result of the limited overall potential benefit to us specifically due to our commercial arrangement with Takeda and them taking over GLASSIA manufacturing in 2021.

Strategic Partnerships

We currently have strategic partnerships with a number of different companies regarding the distribution and/or development of our products portfolio. Certain of the strategic partnerships relating to our Proprietary Products segment are discussed below.

Takeda (GLASSIA)

We have a partnership arrangement with Takeda. The partnership agreement was originally executed on August 23, 2010 with Baxter. During 2015, Baxter assigned all its rights under the partnership agreement to Baxalta, an independent public company which spun-off from Baxter. In 2016, Shire completed the acquisition of Baxalta, and as a result, all of Baxalta's rights under the partnership agreement were assigned to Shire. In January 2019, Takeda completed its acquisition of Shire.

The partnership arrangement with Takeda includes three main agreements: (1) an exclusive manufacturing, supply and distribution agreement, pursuant to which we manufacture GLASSIA for sale to Takeda for further distribution in the United States, Canada, Australia and New Zealand; (2) a technology license agreement, which grants Takeda licenses to use our knowledge and patents to produce, develop and sell GLASSIA; and (3) a fraction IV-I paste supply agreement, pursuant to which Takeda will supply us with fraction IV plasma, a plasma derivative, produced by Takeda, as discussed under "— Manufacturing and Supply — Raw Materials — Fraction IV plasma for GLASSIA." As between us and Takeda, other than with respect to plasma-derived AAT administration by IV, we retain all rights, including distribution rights, to any form of AAT administration, including Inhaled AAT for AATD."

Sales to Takeda accounted for approximately 49%, 54% and 56% of our total revenues for the years ended December 31, 2020, 2019 and 2018, respectively.

Exclusive Manufacturing, Supply and Distribution Agreement

Pursuant to the exclusive manufacturing, supply and distribution agreement, we received an upfront and milestone payments of $25 million in total related to distribution rights. Additionally, Takeda is obligated to purchase a minimum amount of GLASSIA per year. Under the agreement, Takeda is also obligated to fund required Phase 4 clinical trials related to GLASSIA up to a specified amount. If the costs of such clinical trials are in excess of this amount, we have agreed to fund a portion of the additional costs. Under the agreement, we undertook to reimburse Takeda for its GLASSIA marketing efforts up to a limited amount during the years 2017-2020. During the years since the initial execution of the agreement, the parties agreed to several amendments to the agreement, mainly related to supply quantities of GLASSIA by us to Takeda and transfer pricing. On August 30, 2019, we signed the sixth amendment to the exclusive manufacturing, supply and distribution agreement with Takeda to extend the period of minimum purchases by Takeda of GLASSIA until the end of 2021 and increase the minimum purchases under the distribution agreement. Our 2020 revenues from the sale of GLASSIA to Takeda totaled $64.9 million and we project that total revenues from sales of GLASSIA to Takeda for 2021 will be approximately $25 million, which is Takeda's minimum commitment for 2021 pursuant to the agreement with Takeda. According to the terms of the agreement, following its compliance with its purchasing obligations until the end of 2021, Takeda will have no further obligation to purchase a minimum amount of GLASSIA.

Pursuant to the technology license agreement described below, Takeda is planning to complete the technology transfer of GLASSIA manufacturing, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021, following which we do not anticipate to continue to manufacture and supply GLASSIA to Takeda under the exclusive manufacturing, supply and distribution agreement.

The distribution agreement expires in 2040. In addition to customary termination provisions, either party may terminate the agreement, subject to certain exceptions, in whole or solely with respect to one or more countries covered by the distribution agreement, if regulatory approval in one or more countries covered by the distribution agreement is withdrawn or rejected and not reversed. Takeda has the right to terminate the agreement, upon prior written notice and after a period of time, in the event that GLASSIA is determined to materially infringe upon a third party's intellectual property rights. In addition to the minimum purchase termination right discussed above, we have the right to terminate the agreement upon prior written notice if Takeda infringes upon our intellectual property.

See "Item 3. Key Information — D. Risk Factors — *With the cessation of production of GLASSIA for Takeda in 2021, our revenues and profitability will decrease."*

Technology License Agreement

The technology license agreement provides an exclusive license to Takeda, with the right to sub-license to certain manufacturing parties, of our intellectual property and know-how regarding the manufacture and additional development of GLASSIA for use in Takeda's production and sale of GLASSIA in the United States, Canada, Australia and New Zealand. Pursuant to the technology license agreement, we are entitled to receive payments for the achievement of certain milestones for an aggregate of up to $20.0 million, of which $15.0 million are development-based milestones related to the transfer of technology to Takeda and $5.0 million are sales-based milestones. To date, we have received $15 million of the total aggregate milestone payments under the agreement.

Takeda will complete the technology transfer of GLASSIA manufacturing, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021. Accordingly, based on the technology license agreement between the companies, and in addition to the above mentioned milestone payments, upon initiation of commercial sales of GLASSIA manufactured by Takeda, Takeda will pay royalties to us at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040.

The intellectual property rights for any improvements on the manufacturing process or formulations that we disclose to Takeda belong to the party that develops the improvements, with each party agreeing to cross-license the developed improvements to the other party. We retain an option to license any intellectual property developed by Takeda under the agreement that is not considered an improvement on the licensed technology. Additionally, Takeda owns any intellectual property it develops using the licensed technology for new indications for the intravenous AAT product, for which we retain an option to license at rates to be negotiated. Any technology related to new indications for the intravenous AAT product developed by us during the royalty payments period will be part of the licensed technology covered by the technology license agreement.

The technology license agreement expires in 2040. Either party may terminate the agreement, in whole or solely with respect to one or more countries covered by the distribution agreement, pursuant to customary termination provisions. Takeda also has the right to terminate the agreement, upon prior written notice, in the event that: (i) our manufacturing process technology for GLASSIA is determined to materially infringe upon a third party's intellectual property rights, and we have not obtained a license to such third party's intellectual property or provided an alternative non-infringing manufacturing process; (ii) there are certain decreases in GLASSIA sales in the United States unless such decreases are due to transfers to Inhaled AAT for AATD; or (iii) the regulatory approval process in the United States has been withdrawn or rejected as a result of our inaction or lack of diligent effort, provided such withdrawal or rejection was not primarily caused by the breach by Takeda of its obligations. We have the right to terminate the agreement, upon prior written notice: (i) if Takeda contests or infringes upon our intellectual property; (ii) if regulatory approval in one or more countries covered by the technology license agreement is withdrawn or rejected and not reversed, provided it was not primarily caused by the breach by us of our obligations; (iii) in the event that GLASSIA produced by Takeda, other than as a result of our manufacturing process technology, is determined to materially infringe upon a third party's intellectual property rights, provided that the termination right is limited only to the country in which such judgment is binding; or (iv) if the first sale of GLASSIA produced by Takeda did not occur by June 15, 2017 and Takeda has not used commercially reasonable efforts to sell by that date. Following any termination, other than expiration of the agreement, all licensed rights will revert to us. Upon expiration of the agreement, we are obligated to grant to Takeda a non-exclusive, perpetual, royalty free license.

Kedrion (KEDRAB and Anti-SARS-CoV-2)

On July 18, 2011, we signed an agreement with Kedrion, an international pharmaceutical company engaged in the manufacture of life-saving drugs based on human plasma which complement our products, and which are marketed in Europe, the United States and approximately 40 other countries worldwide. The agreement provides for exclusive cooperation on completing the clinical development, and marketing and distribution of our anti-rabies pharmaceutical, KamRAB, in the United States under the name KEDRAB, if the product is approved. Pursuant to the agreement, Kedrion bore all the costs of the Phase 2/3 clinical trials in the United States of our product for rabies. Costs related to any Phase 4 clinical trials, if required, and the FDA Prescription Drug User fee that is required for all FDA new drug approvals, will be divided equally between us and Kedrion. An addendum to the agreement was executed dated as of October 15, 2016, with respect to the performance of a safety clinical trial for the treatment of pediatric patients in the United States. According to such addendum, Kedrion and us agreed to equally share the cost of such trial. A second addendum to the agreement was executed dated as of October 11, 2018, with respect to the purchase prices of KEDRAB under the agreement.

The agreement provides exclusive rights to Kedrion to market and sell KEDRAB in the United States. We retain intellectual property rights to KEDRAB. Kedrion is obligated to purchase a minimum amount of KEDRAB per year during the term of the agreement.

In 2014, the Phase 2/3 study was completed and successfully met the trial's primary endpoint of non-inferiority when measured against an IgG reference product, and in September 2016, the BLA was submitted to the FDA. In August 2017, we received FDA approval of anti-rabies immunoglobulin as a post-exposure prophylaxis against rabies infection. In April 2018, we launched KEDRAB in the United States. See "Item 4. Information on the Company — *Proprietary Products Segment — KamRAB/KEDRAB*". Our overall revenues from the sales of KEDRAB to Kedrion during 2020, 2019 and 2018 were $18.3 million, $16.4 million and $11.8 million, respectively. Sales of KEDRAB by Kedrion in the United States during the years 2020, 2019 and 2018 totaled $23.7 million, $31.4 million and $15.5 million, respectively. Based on information provided by Kedrion, these sales represent approximately 23%, 20% and 10% share of the relevant U.S. market in each of these years, respectively. The decrease in sales of KEDRAB by Kedrion during 2020 is attributable to the impact of the COVID-19 pandemic.

The term of the agreement is for six years following the receipt of FDA approval, subject to Kedrion's option to extend the agreement by two years. In addition to customary termination provisions, either party can terminate the agreement for any reason prior to the commencement of clinical trials for FDA approval. Kedrion also has the right to terminate the agreement, upon prior written notice, (i) for any reason after receipt of FDA approval, (ii) in the event that the FDA Biologics License Application is suspended or revoked and cannot be reinstated within a certain period of time, or (iii) a major regulatory change occurs that materially and adversely increases the clinical trial costs. We have the right to terminate the agreement in the event that (i) a major regulatory change occurs that materially and adversely increases the manufacturing costs of KEDRAB, (ii) a major regulatory change occurs that poses considerable difficulties on submission of an application for FDA approval or (iii) clinical trials are not initiated within a certain time after either receipt by Kedrion of enough product or FDA approval to begin clinical trials.

In April 2020, we entered into a binding term sheet for the co-development, manufacturing and distribution of a human plasma-derived Anti-SARS-CoV-2 polyclonal immunoglobulin (IgG) product as a potential treatment for COVID-19 patients. The plasma-derived Anti-SARS-CoV-2 IgG product will be developed and manufactured utilizing our proprietary IgG platform technology. Pursuant to the agreed terms, Kedrion will provide plasma, collected at its KEDPLASMA centers, from donors who have recovered from the virus and, upon receipt of regulatory approvals, will be responsible for commercialization of the product in the U.S., Europe, Australia, South Korea, United Kingdom, Switzerland and Norway. We are responsible for product development, manufacturing, clinical development, with Kedrion's support, and regulatory submissions. We will also assume distribution responsibility in all territories outside of those Kedrion is responsible for. Marketing rights for the product in China will be shared by the parties. The binding term sheet shall remain in full force and effect until the definitive agreements are executed by the parties, or at the latest until June 30, 2021, unless early terminated by mutual agreement of the parties.

PARI

On November 16, 2006, we entered into a license agreement with PARI (the "Original PARI Agreement") regarding the clinical development of an inhaled formulation of AAT, including Inhaled AAT for AATD, using PARI's "eFlow" nebulizer. Under the Original PARI Agreement, we received an exclusive worldwide license, subject to certain preexisting rights, including the right to grant sub-licenses, to use the "eFlow" nebulizer, including the associated technology and intellectual property, for the clinical development, registration and commercialization of inhaled formulations of AAT to treat AATD and respiratory deterioration, and to commercialize the device for use with such inhaled formulations. The agreement also provided for PARI's cooperation with us during the pre-clinical phase and Phase 1 clinical trials of Inhaled AAT, where each of the parties was responsible for developing and adapting its own product and bore the costs involved.

Pursuant to the Original PARI Agreement, we agreed to pay PARI royalties from sales of Inhaled AAT, after certain deductions, at the rates specified in the agreement. We have agreed to pay PARI tiered royalties ranging from the low single digits up to the high single digits based on the annual net sales of inhaled formulations of AAT for the applicable indications. The royalties will be paid for each country separately, until the later of (1) the expiration of the last of certain specified patents covering the "eFlow" nebulizer, or (2) 15 years following the first commercial sale of an inhaled formulation of AAT in that country (the "PARI royalties period"). During the PARI royalties period, PARI is obligated to pay us specified percentages of its annual sales of the "eFlow" nebulizer for use with Inhaled AAT above a certain threshold defined in the agreement and after certain deductions. On February 21, 2008, we entered into an addendum to the Original PARI Agreement (together with the Original PARI Agreement, the "PARI Agreement"), which extended the exclusive global license granted to us to use the "eFlow" nebulizer, including the associated technology and intellectual property, for the clinical development, registration and commercialization of Inhaled AAT for two additional indications of lung disease, namely cystic fibrosis and bronchiectasis. At present, the development of cystic fibrosis and bronchiectasis products is suspended as we prioritize other products. Pursuant to the addendum, each party will be responsible for developing and adapting its own product for the additional indications and will bear the costs involved. Additionally, we and PARI will supply, each at its own expense, Inhaled AAT and the "eFlow" nebulizers, respectively, and in the quantities required for all phases of clinical studies worldwide. In addition, PARI will provide to us, at its expense, technical and regulatory support regarding the "eFlow" nebulizer. Sales of the inhaled formulation of AAT for the additional indications will be added to sales of the first two indications covered by the original agreement as the basis for calculating the royalties to be paid by us to PARI.

The PARI Agreement expires when the PARI royalties period ends. Either party can terminate the PARI Agreement upon customary termination provisions. Additionally, upon the occurrence of any one of the following events, PARI has the right to negotiate with us in good faith about whether to continue our collaboration: (i) PARI's costs of the required clinical trials exceed a certain amount, unless we or a third party incurs such expenses on behalf of PARI; (ii) an inhaled formulation of AAT is not successfully registered with any regulatory authorities by 2016; (iii) there are no commercial sales of inhaled formulations of AAT within a certain period after successful registration with any regulatory authority; or (iv) we cease development of inhaled formulations of AAT for a certain period of time. If, within 180 days of PARI's request to negotiate, we do not agree to continue the collaboration, PARI has the option either to render the license they grant to us non-exclusive or to terminate the agreement. We have the right to terminate the agreement, upon prior written notice, (i) in the event that the "eFlow" nebulizer is determined to infringe upon a third party's intellectual property rights, (ii) an injunction barring the use of the "eFlow" nebulizer has been in place for a certain period of time, (iii) a clinical trial for inhaled formulations of AAT fails as a result of, after a cure period, the "eFlow" nebulizer not conforming to specifications or PARI's inability to supply the "eFlow" nebulizer; or (iv) failure by PARI to register the "eFlow" nebulizer within a certain period of time after receiving Phase 3 results for Inhaled AAT for AATD. Following any termination, all licensed rights will revert to PARI, unless we terminate the agreement as a result of PARI's bankruptcy, payment failure or material breach, in which case we retain the license rights to the "eFlow" nebulizer as long as we continue making royalty payments.

In addition, in May 2019, we signed a Clinical Study Supply Agreement ("CSSA") with PARI for the supply of the required quantities of PARI's "eTrack" controller kits and the "PARItrack" web portal associated with PARI's "eFlow" nebulizer required for our pivotal Phase 3 InnovAATe clinical trial and for the FDA required HFS. The CSSA is a supplement agreement to the Original PARI Agreement and will expire upon the expiration or termination of the Original PARI Agreement.

On February 21, 2008, we signed a commercialization and supply agreement with PARI that provides for the commercial supply of the "eFlow" nebulizer and its spare parts to patients who are treated with the inhaled formulation of AAT, following its approval, either through its own distributors, our distributors or independent distributors in countries where PARI does not have a distributor. The commercialization and supply agreement expires upon the earlier of (1) the end of four years from (x) the end of the last PARI royalties period, or (y) the termination of the PARI Agreement by one party due to the other party declaring bankruptcy, failing to make a payment after a 30-day cure period or breach of a material provision after a 30-day cure period, or (2) the termination of the PARI Agreement pursuant to its terms, other than for reasons as previously described, in which case the commercialization and supply agreement terminates simultaneously with the PARI Agreement provided that PARI ensures availability of the "eFlow" nebulizer and its associated spare parts and service to anyone being treated with the inhaled formulation of AAT at the time of such termination, for the warranty period of the device or for a longer period, if required by the applicable law or the relevant regulatory authority.

Manufacturing and Supply

We have a production plant located in Beit Kama, Israel. We manufacture all of our proprietary plasma-derived products in this facility. We operate the main production facility on a campaign-basis so that at any time the facility is assigned to produce only one product. The division of facility time among the various products is determined based on orders received, sales forecasts and development needs. During 2014, we completed the build out of a new logistic facility in our plant in Beit Kama that supports our logistic needs. During each year we have routine maintenance shutdowns of our plant, which may last up to a few weeks.

Our production plant passed various health authorities' inspections. The plant was initially inspected by the U.S. FDA during 2010, and in March 2017 the FDA completed an inspection of our facility in connection with our GLASSIA and KEDRAB products with no critical observations. The Israeli MOH conducted a GMP inspections in each of 2011, July 2013, February 2016 and November 2018, with no critical observations. In July 2018, Health Canada (the department of the government of Canada with responsibility for national public health) completed an audit in connection with the KamRAB product, with no critical observations. In February 2019, the Croatian health agency completed a GMP inspection of our facility in connection with GLASSIA and our Inhaled AAT for AATD product, with no critical observations. In March 2019, the Mexican heath agency completed a GMP inspection of our facility in connection with our KamRAB product, which concluded with no critical observations and with a dispute on required corrective actions. The Kazakhstan health agency also completed a GMP inspection in April 2019, with no critical observations. In December 2020, the Israeli MOH completed a GMP inspection with no critical observations.

Any changes in our production processes for our products must be approved by the FDA and/or similar authorities in other jurisdictions. From time to time we make certain required modifications to our manufacturing process and are required to make certain filings to report such changes to the FDA and/or other similar authorities.

Raw Materials

The main raw materials in our Proprietary Products segment are hyper-immune plasma and fraction IV. We also use other raw materials, including both natural and synthetic materials. We purchase raw materials from suppliers who are regulated by the FDA, EMA and other regulatory authorities. Our suppliers are approved in their countries of origin and by the IMOH. The raw materials must comply with strict regulatory requirements. We require our raw materials suppliers to comply with the cGMP rules, and we audit our suppliers from time to time. We are dependent on the regular supply and availability of raw materials in our Proprietary Products segment.

We maintain relationships with several suppliers in order to ensure availability and reduce reliance on specific suppliers. We are dependent, however, on a number of suppliers who supply specialty ancillary products prepared for the production process, such as specific gels and filters. See "Item 3. Key Information — D. Risk Factors — We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements or if prices of the source plasma or plasma derivatives were to raise significantly."

In the years ended December 31, 2020, 2019 and 2018, we incurred $22.9 million, $31.5 million and $25.5 million of expenses for the purchase of raw materials, respectively.

Plasma derived Fraction IV paste for GLASSIA manufacturing

On August 23, 2010, in conjunction with the partnership arrangement with Takeda, we signed a fraction IV paste supply agreement with Takeda for the supply of fraction IV for use in the production of GLASSIA to be sold in the United States. Under this agreement, Takeda also supplies us with fraction IV to continue the development, pre-clinical and clinical studies of GLASSIA and other AAT derived products and for the production, sale and distribution of GLASSIA in jurisdictions other than those which are covered under the exclusive manufacturing, supply and distribution agreement with Takeda as well as for other AAT derived products (e.g., Inhaled AAT). Takeda receives no payment for the supply of fraction IV plasma to be used by us for the manufacture of GLASSIA to be sold to Takeda. If we require fraction IV for other purposes, we are entitled to purchase it from Takeda at a predetermined price.

The supply agreement terminates on August 23, 2040, subject to an option for earlier termination in the event of a material breach.

We have an additional fraction IV plasma supplier, approved for production of GLASSIA marketed in non-U.S. countries. We are in the process of exploring the entry into a long-term supply agreements for fraction IV plasma with additional suppliers.

Hyper-immune Plasma

We have a number of suppliers in the United States for hyper-immune plasma with which we have long-term supply agreements. Hyper-immune plasma is used for the production of KamRAB/KEDRAB and KamRho(D), as well as our Anti-SARS-CoV-2 IgG product currently under development. In addition to long-term supply agreements, we work to secure availability of hyper-immune plasma on an annual basis by providing forecasts to our suppliers based on our customers' actual and forecasted orders. We continue to seek to enter into long-term supply agreements for hyper-immune plasma with additional plasma-collection companies.

In January 2012, we entered into a plasma purchase agreement with KedPlasma, a subsidiary of Kedrion, for the supply of anti-rabies hyper-immune plasma required for the manufacturing of KamRAB (including for manufacturing of KEDRAB for sale to Kedrion for further distribution in the U.S. market). The agreement provides for a commitment to supply certain minimum annual quantities at predetermined prices. We are currently negotiating a renewal of the agreement terms.

Pursuant to the global collaboration engagement with Kedrion for the co-development, manufacturing and distribution of our Anti-SARS-CoV-2 IgG product as a potential treatment for COVID-19 patients, Kedrion through its subsidiary, KEDPLASMA, is supplying us plasma from U.S. donors who have recovered from COVID-19 to be used for the development and manufacturing of the Anti-SARS-CoV-2 IgG product. In addition, per our Anti-SAR-CoV-2 supply agreement with the IMOH, we will receive convalescent plasma collected and supplied by the Israeli National Blood Services, a division of Magen David Adom (MADA).

In line with our strategy to become vertically integrated plasma-derived company through the development and/or acquisition of plasma collection, during January 2021, we entered into an agreement for the acquisition, subject to customary closing conditions, of the assets, licenses and business of B&PR, an FDA-licensed plasma collection center located in Beaumont, TX. We plan to invest in growing the site's collection volume and to leverage its FDA license to open additional collection centers, significantly growing our overall hyperimmune plasma collection capacity.

Marketing and Distribution

In the Proprietary Products segment, we receive orders for our products and, other than for GLASSIA and KEDRAB sales in the U.S. market, we received requests for participation in tenders for the supply of plasma-derived protein therapeutics from potential distributors and from existing distributors. We sell GLASSIA to Takeda for further distribution in the U.S. market (however, given the transition of GLASSIA manufacturing to Takeda, we do not expect to continue to sell GLASSIA to Takeda after 2021), and sell to other distributors in additional non-U.S. countries. We sell KEDRAB to Kedrion for distribution in the U.S. market and sell KamRAB and KamRho to other distributers in additional non-U.S. countries. Pursuant to an agreement with the IMOH, we expect to supply certain quantities of our investigational Anti-SARS-CoV-2 IgG product to the IMOH during 2021.

For our products, we market, in most cases, by means of agreements with local distributors in each country through a tender process and/or the private market. The tender process is conducted on a regular basis by the distributors, sometimes on an annual basis. For existing customers, our existing relationship does not guarantee additional orders from the same customers in these tenders. The decisive parameter is generally the price proposed in the tender. The distributor purchases plasma-derived protein therapeutics from us and sells them to its customers (either directly or by means of sub-distributors). In most cases, we do not sign agreements with the end users, and as such, we do not fix the price to the end user or its terms of payment and are not exposed to credit risks of the end users. In the vast majority of cases, our agreements with the local distributors award the various distributors exclusivity in the distribution of our plasma-derived protein therapeutics in the relevant country. The distribution agreements are, usually made for a specific initial period and are subsequently renewed for certain agreed periods, where the parties have the right to cancel or renew the agreements with prior notice of a number of months. In these markets, we do not actively participate in the marketing to the end users, except for supplying marketing assistance where the cost is negligible or in some cases, reimburse the local distributor for an agreed amount of its actual marketing expenses. In Israel, we market our plasma-derived protein therapeutics independently to the healthcare providers and medical centers, or through a logistic partner company that specializes in the supply of equipment and pharmaceuticals to healthcare providers.

Most of our sales outside of Israel are made against open credit and some in documentary credit or advance payment. Most of our sales inside Israel are made against open credit or cash. The credit given to some of our customers abroad (except for sales in documentary credit or advanced payment) is mostly secured by means of a credit insurance policy and in certain cases with bank guarantees.

In the Distribution segment, we market our products in Israel to HMOs and hospitals on our own or through third party logistic associates. We sell certain of our Distribution segment products through offers to participate in public tenders that occur on an annual basis or through direct orders. The public tender process involves HMOs and hospitals soliciting bids from several potential suppliers, including us, and selecting the winning bid based on several attributes, the primary attributes are generally price and availability. The annual public tender process is also used by our existing customers to determine their suppliers. As a result, our existing relationships with customers in our Distribution segment do not guarantee additional orders from such customers year to year.

We have supply and distribution agreements with our suppliers in our Distribution segment, including with each of our two largest suppliers to be their exclusive distributor in Israel for a number of their manufactured products; however, we purchase our Distribution segment products from those suppliers on a purchase order basis. We work closely with those suppliers to develop annual forecasts, but these forecasts do not obligate our suppliers to provide us with their products.

Customers

For the year ended December 31, 2020, sales to our three largest customers, Takeda, Kedrion and Clalit Health Services, an Israeli HMO, accounted for 49%, 14% and 10%, respectively, of our total revenues. For the year ended December 31, 2019, sales to Takeda, Kedrion and Clalit Health Services, an Israeli HMO, accounted for 54%, 13% and 11%, respectively, of our total revenues. For the year ended December 31, 2018, sales to Takeda and Kedrion accounted for 56% and 10%, respectively, of our total revenues.

Takeda and Kedrion are currently our major customers in the Proprietary Products segment. Our other customers in the Proprietary Products segment are our distributors in Argentina, Russia, Thailand, India and Brazil as well as HMOs and medical centers in Israel. In other geographies, most of the sales of our products are conducted through local distributors. These arrangements are further described above under "— Marketing and Distribution."

Our primary customers in the Distribution segment are HMOs and hospitals in Israel, including Clalit Health Services and Maccabi Healthcare Services.

Competition

The worldwide market for pharmaceuticals in general, and biopharmaceutical and plasma products in particular, has in recent years undergone a process of mergers and acquisitions among companies active in such markets. This trend has led to a reduction in the number of competitors in the market and the strengthening of the remaining competitors, mainly for specific immunoglobulin products.

Proprietary Products Segment

We believe that there are several competitors for each of our products in the Proprietary Products segment. These competitors include CSL Behring Ltd., Grifols S.A., which acquired a previous competitor, Talecris Biotherapeutics, Inc. in 2011, Octapharma and Kedrion (other than for KEDRAB). These competitors are multi-national companies that specialize in plasma derived protein therapeutics and are distributing their plasma derived pharmaceutical products worldwide. We have not seen significant changes in the activities of our competitors in recent years. Additionally, our strategic alliance with Takeda and Kedrion in the United States has strengthened our GLASSIA and KEDRAB competitive positioning in the market.

Our competitors have advantages in the market because of their size, financial resources, markets and the duration of their activities and experience in the relevant market, especially in the United States and countries of the European Union. Most of them have an additional advantage regarding the availability of raw materials, as they fractionate plasma internally and own plasma collection centers and/or companies that collect or produce raw materials such as plasma.

The following describes details known to us about our most significant competitors for each of our main Proprietary Products segment products.

GLASSIA. GLASSIA has several competitors, including plasma derived companies such as Grifols, CSL and Takeda, all of which have competing plasma derived AAT products approved for AATD and are marketed in the U.S. as well in some countries in the EU. We estimate that: Grifols' AAT by infusion product for the treatment of AATD, Prolastin, accounts for at least 50% market share in the United States and more than 70% of sales worldwide. In September 2017, Grifols announced that the FDA approved a liquid formulation of its AAT product. Apart from its sales of the past Talecris product, Grifols is also a local producer of an additional AAT product, Trypsone, which is marketed in Spain and in some Latin American countries, including Brazil. CSL's AAT by IV product, Zemaira, is mainly sold in the United States, and during 2015 received centralized marketing authorization approval in the European Union. CSL launched the product in few selected EU markets during 2016 under the brand name Respreeza. Takeda is our strategic partner for sales of GLASSIA and it also serves existing patients in the United States with its own proprietary product, Aralast. As far as we know, Takeda is proactively marketing both products in the United States, and currently maintaining existing patients on Aralast. In addition, we are aware of a local producer of AAT in the French market, Laboratoire Français du Fractionnement et des Biotechnologies, S.A. (LFB). We do not believe any new suppliers are expected to enter the United States market for plasma derived AAT by infusion in the near future.

In addition, we have several other competitors such as Vertex Pharmaceuticals, Inhibrx, ApicBio and Mereo, all of which have development stage programs for new medications for treatment of AATD. Based on available public information, Vertex, a Boston, MA headquartered company, is in early-stage clinical development of VX-864, a small molecule utilizing a correction approach to prevent protein misfolding in the liver of AATD patients, which can otherwise aggregate and ultimately be pro-inflammatory in the liver. Vertex believes small molecule correctors for protein misfolding could address both liver and lung disease manifestations, possibly avoiding the need for conventional augmentation therapy, further differentiating its product candidates as a novel therapeutic approach. Inhibrx, a California based company, is in early clinical development of INBRX-101 a recombinantly produced AAT replacement protein specifically designed to address some limitations of plasma derived AAT replacement therapy. The modifications introduced into INBRX-101 aim to improve the pharmacokinetic profile (PK) and obliterate inactivation through oxidation. This could offer superior clinical activity to the current commercial plasma derived AAT by providing sustained enhanced serum concentration with a less frequent, monthly dosing regimen. Apic Bio, a Boston, MA based company is in pre-clinical stage development of APB-101 a "liver-sparing" gene therapy designed for treatment of Alpha-1 patients. In pre-clinical studies, APB-101 demonstrated the ability to reduce levels of the mutant Alpha-1 protein (Z-AAT) and at the same time program liver cells to produce the correct Alpha-1 protein (M-AAT). Mereo, a UK based company, is in clinical stage of development of MPH-966 as an oral neutrophil elastase inhibitor being explored for the potential treatment of AATD. These product candidates, if approved, may have an adverse effect on the AATD market and reduce or eliminate the need for the currently approved plasma derived AAT augmentation therapy, and thus may affect our ability to continue and generate revenues and earnings from our GLASSIA. In addition, these product candidates, if approved, may have a negative effect on our ability to continue the development of our Inhaled AAT, and if approved, to market Inhaled AAT and obtain a meaningful market share.

KamRAB/KEDRAB. We believe that there are two main competitors for this anti-rabies product worldwide: Grifols, whose product we estimate comprises of approximately 70%-80% of the anti-rabies market in the United States, and CSL, which sells its anti-rabies product in Europe and elsewhere. Sanofi Pasteur, the vaccines division of Sanofi S.A., has a product registered for the United States market, but the product is primarily sold in Europe and not currently sold in significant quantities in the United States. There are a number of local producers in other countries that make similar anti-rabies products. Most of these products are based on equine serum, which we believe results in inferior products, as compared to products made from human plasma. Over the past several years, a number of companies have made attempts, and some are still in the process of developing monoclonal antibodies for an anti-rabies treatment. The first monoclonal antibody product was approved and is available in India. These products may be as effective as the currently available plasma derived anti-rabies vaccine and may potentially be significantly cheaper, and as such may result in loss of market share of KamRAB/KEDRAB.

KamRho(D). While Kedrion is our strategic partners for KEDRAB, it is also one of our competitors for KamRho(D). In addition to its sales in the United States, Kedrion also markets a competing product in several EU countries as well as other countries world-wide. We believe there are three additional main suppliers of competitive products in this market: Grifols, CSL and Saol Therapeutics. There are also local producers in other countries that make similar products mostly intended for local markets.

Anti-SARS-CoV-2 IgG for COVID-19. In the wake of the COVID-19 pandemic, the CoVIg-19 Plasma Alliance partnership (the Alliance") was formed of the world's leading plasma companies, spanning plasma collection, development, production and distribution with the goal to accelerate the development of a potential treatment, and increase supply of the potential treatment. In addition to Biotest, BPL, CSL Behring, LFB, Octapharma and Takeda all of which formed the Alliance, the following additional industry members have reportedly joined the Alliance: ADMA Biologics, BioPharma Plasma, GC Pharma, Liminal BioSciences and Sanquin. The Alliance is developing a plasma derived hyperimmune therapy for COVID-19 that is based on plasma collected from convalescent COVID-19 patients, which is similar to our Anti-SARS-CoV-2 investigational IgG product. In addition, the Alliance recently announced the initiation of the ITAC Phase 3 clinical trial sponsored by the NIAID, part of the NIH, which will evaluate the safety, tolerability and efficacy of an investigational anti-coronavirus hyperimmune intravenous immunoglobulin (H-Ig) medicine for treating hospitalized adults at risk for serious complications of COVID-19 disease. If successful, the Alliance's product may become one of the earliest treatment options for hospitalized COVID-19 patients. This product, if approved, may affect our ability to launch and/or market our Anti-SARS-CoV-2 investigational IgG product, if approved.

In addition, a number of companies are in the process of advanced development of monoclonal antibodies for an Anti-SARS-CoV-2 treatment, such as Regeneron's casirivimab and imdevimab which form a novel monoclonal antibody cocktail being studied for its potential both to treat appropriate patients with COVID-19 and to prevent SARS-CoV-2 infection, and Eli Lilly's investigational neutralizing antibody bamlanivimab (LY-CoV555) 700 mg. Bamlanivimab which received emergency use authorization from the FDA for the treatment of mild to moderate COVID-19 in adults and pediatric patients 12 years and older with a positive COVID-19 test, who are at high risk for progressing to severe COVID-19 and/or hospitalization. Moreover, the FDA recently issued an Emergency Use Authorization for convalescent plasma as a potential treatment for COVID–19. Convalescent plasma plays an important role in the immediate and intermediate response to the disease. These products and other similar products may be as effective as our plasma derived IgG product, may obtain approval for the FDA, EMA or other regulatory agencies sooner than our product, may be significantly cheaper, and as such may affect our ability to launch and/or gain sufficient market share with our Anti-SARS-CoV-2 investigational IgG product, if approved.

Distribution Segment

We believe that there are a number of companies active in the Israeli market distributing the products of several manufacturers whose comparable products compete with our products in the Distribution segment. In the plasma area, these manufacturers include Grifols, Takeda, CSL, Omrix Biopharmaceuticals Ltd. (a Johnson & Johnson company), while in other specialties and biosimilar products we may be competing against products produced by some of largest pharmaceutical manufacturers in the world, such as, Novartis AG, AstraZeneca AB, Sanofi UK and GlaxoSmithKline. These competing manufacturers have advantages of size, financial resources, market share, broad product selection and extensive experience in the market, although we believe that we have established expertise in the Israeli market. Each of these competitors sells its products through a local subsidiary or a local representative in Israel.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we sell and are developing. Except for compassionate use or non-registered named-patient cases, any pharmaceutical candidate that we develop must be approved by the FDA before it may be legally marketed in the United States and by the appropriate regulatory agencies of other countries before it may be legally marketed in such other countries. In addition, any changes or modifications to a product that has received regulatory clearance or approval that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, may require the submission of a new application in the United States and/or in other countries for pre-market approval. The process of obtaining such approvals can be expensive, time consuming and uncertain.

U.S. Drug Development Process

In the United States, pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. All of our products for human use and product candidates in the United States, including GLASSIA, are regulated by the FDA as biologics. Biologics require the submission of a BLA and approval or license by the FDA prior to being marketed in the United States. Manufacturers of biologics may also be subject to state regulation. Failure to comply with regulatory requirements, both before and after product approval, may subject us and/or our partners, contract manufacturers and suppliers to administrative or judicial sanctions, including FDA delay or refusal to approve applications, warning letters, product recalls, product seizures, import restrictions, total or partial suspension of production or distribution, fines and/or criminal prosecution.

The steps required before a biologic drug may be approved for marketing for an indication in the United States generally include:

1. preclinical laboratory tests and animal tests;

2. submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may commence;

3. adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;

4. submission to the FDA of a BLA or supplemental BLA;

5. FDA pre-approval inspection of product manufacturers; and

6. FDA review and approval of the BLA or supplemental BLA.

Preclinical studies include laboratory evaluation, as well as animal studies to assess the potential safety and efficacy of the product candidate. Preclinical safety tests must be conducted in compliance with FDA regulations regarding good laboratory practices. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND which must become effective before human clinical trials may be commenced. The IND will automatically become effective 30 days after receipt by the FDA, unless the FDA before that time raises concerns about the drug candidate or the conduct of the trials as outlined in the IND. The IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials or that, once commenced, other concerns will not arise that could lead to a delay or a hold on the clinical trials.

Clinical trials involve the administration of the investigational product to healthy volunteers or to patients, under the supervision of qualified principal investigators. Each clinical study at each clinical site must be reviewed and approved by an independent institutional review board, prior to the recruitment of subjects. Numerous requirements apply including, but not limited to, good clinical practice regulations, privacy regulations, and requirements related to the protection of human subjects, such as informed consent.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap and different trials may be initiated with the same drug candidate within the same phase of development in similar or differing patient populations.

- Phase 1 studies may be conducted in a limited number of patients, but are usually conducted in healthy volunteer subjects. The drug is usually tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmacodynamics and pharmacokinetics.

- Phase 2 usually involves studies in a larger, but still limited, patient population to evaluate preliminarily the efficacy of the drug candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible short-term adverse effects and safety risks.

- Phase 3 trials are undertaken to further evaluate clinical efficacy of a specific endpoint and to test further for safety within an expanded patient population at geographically dispersed clinical study sites.

Phase 1, Phase 2 or Phase 3 testing may not be completed successfully within any specific time period, if at all, with respect to any of our product candidates. Results from one trial are not necessarily predictive of results from later trials, the FDA may require additional testing or a larger pool of subjects beyond what we proposed as the clinical development process proceeds, thereby requiring more time and resources to complete the trials. Furthermore, the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk, or may not allow the importation of the clinical trial materials if there is non-compliance with applicable laws.

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of a BLA requesting approval to market the product candidate for a proposed indication. Under the Prescription Drug User Fee Act, as amended, the fees payable to the FDA for reviewing a BLA, as well as annual fees for commercial manufacturing establishments and for approved products, can be substantial. The BLA review fee alone can exceed $2,800,000, subject to certain limited deferrals, waivers and reductions that may be available. Each BLA submitted to the FDA for approval is typically reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If found complete, the FDA will "file" the BLA, thus triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. The FDA's established goals are to review and act on 90% of priority BLA applications and priority original efficacy supplements within six months of the 60-day filing date and receipt date, respectively. The FDA's goals are to review and act on 90% of standard BLA applications and standard original efficacy supplements within 10 months of the 60-day filing date and receipt date, respectively. The FDA, however, may not be able to approve a drug within these established goals, and its review goals are subject to change from time to time. Further, the outcome of the review, even if generally favorable, may not be an actual approval but an "action letter" that describes additional work that must be done before the application can be approved. Before approving a BLA, the FDA may inspect the facilities at which the product is manufactured or facilities that are significantly involved in the product development and distribution process, and will not approve the product unless cGMP compliance is satisfactory. The FDA may deny approval of a BLA if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can delay the approval process. FDA approval of any application may include many delays or never be granted. If a product is approved, the approval will impose limitations on the indicated uses for which the product may be marketed, will require that warning statements be included in the product labeling, may impose additional warnings to be specifically highlighted in the labeling (e.g., a Black Box Warning), which can significantly affect promotion and sales of the product, may require that additional studies be conducted following approval as a condition of the approval, may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. To market a product for other uses, or to make certain manufacturing or other changes requires prior FDA review and approval of a BLA Supplement or new BLA. Further post-marketing testing and surveillance to monitor the safety or efficacy of a product is required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

As part of the Patient Protection and Affordable Care Act (the "healthcare reform law"), Public Law No. 111-148, under the subtitle of Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), a statutory pathway has been created for licensure, or approval, of biological products that are biosimilar to, and possibly interchangeable with, earlier biological products approved by the FDA for sale in the United States. Also under the BPCIA, innovator manufacturers of original reference biological products are granted 12 years of exclusive use before biosimilars can be approved for marketing in the United States. There have been proposals to shorten this period from 12 years to seven years. The objectives of the BPCI are conceptually similar to those of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Act," which established abbreviated pathways for the approval of drug products. A biosimilar is defined in the statute as a biological product that is highly similar to an already approved biological product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the approved biological product in terms of the safety, purity, and potency. Under this approval pathway, biological products can be approved based on demonstrating they are biosimilar to, or interchangeable with, a biological product that is already approved by the FDA, which is called a reference product. If we obtain approval of a BLA, the approval of a biologic product biosimilar to one of our products could have a significant impact on our business. The biosimilar product may be significantly less costly to bring to market and may be priced significantly lower than our products.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the BLA for the product are subject to comprehensive regulatory oversight. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP requirements, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP compliance. In addition, a BLA holder must comply with post-marketing requirements, such as reporting of certain adverse events. Such reports can present liability exposure, as well as increase regulatory scrutiny that could lead to additional inspections, labeling restrictions, or other corrective action to minimize further patient risk.

Special Development and Review Programs

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States. In the United States, orphan drug designation must be requested before submitting a BLA or supplemental BLA.

In the European Union, the Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union community. Additionally, this designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product.

We received an orphan drug designation in the United States and Europe for multiple indications. Inhaled AAT for AATD has received an orphan drug designation in the United States and Europe. The inhaled formulation of AAT for the treatment of cystic fibrosis has received an orphan drug designation in the United States and Europe. The inhaled formulation of AAT for the treatment of bronchiectasis has received an orphan drug designation in the United States. The additional indication for GLASSIA for the treatment of newly diagnosed cases of Type-1 Diabetes has received an orphan drug designation in the United States. In addition, the indication for AAT for the treatment of Graft versus Host Disease has received an orphan drug designation in the United States and Europe, and the indication for AAT for the treatment of Prophylactic Graft versus Host Disease has received an orphan drug designation in the United States.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product and its active ingredients receive the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. In addition, the FDA may rescind orphan drug designation and, even with designation, may decide not to grant orphan drug exclusivity even if a marketing application is approved. Furthermore, the FDA may approve a competitor product intended for a non-orphan indication, and physicians may prescribe the drug product for off-label uses, which can undermine exclusivity and hurt orphan drug sales. There has also been litigation that has challenged the FDA's interpretation of the orphan drug exclusivity regulatory provisions, which could potentially affect our ability to obtain exclusivity in the future.

In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or a safer, more effective or otherwise clinically superior product is available.

In the European Union, an application for marketing authorization can be submitted after the application for orphan drug designation has been submitted, while the designation is still pending, but should be submitted prior to the designation application in order to obtain a fee reduction. Orphan drug designation does not convey any advantage in except eligibility to conditional approval process, or shorten the duration of, the regulatory review and approval process.

Post-Approval Requirements

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA. Certain requirements include, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information on an annual basis or more frequently for specific events, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. These promotion and advertising requirements include, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), and other promotional activities. Failure to comply with FDA requirements can have negative consequences, including the immediate discontinuation of noncomplying materials, adverse publicity, warning letters from or other enforcement by the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Such enforcement may also lead to scrutiny and enforcement by other government and regulatory bodies. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not encourage, market or promote such off-label uses.

The manufacturing of our product candidates is required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. Our product candidates are either manufactured at our production plant in Beit Kama, Israel, or, for products where we have entered into a strategic partnership with a third party to cooperate on the development of a product candidate, at a third-party manufacturing facility. These regulations require, among other things, quality control and quality assurance, as well as the corresponding maintenance of comprehensive records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also required to register their establishments and list any products they make with the FDA and to comply with related requirements in certain states. These entities are further subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in serious and extensive restrictions on a product, manufacturer or holder of an approved BLA, as well as lead to potential market disruptions. These restrictions may include suspension of a product until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a "consent decree," which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval, including possible user fees.

The FDA also may require a Boxed Warning (e.g., a specific warning in the label to address a specific risk, sometimes referred to as a "Black Box Warning"), which has marketing restrictions, and post-marketing testing, or Phase 4 testing, as well as a Risk Evaluation and Minimization Strategy (REMS) plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of the product.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation and enforcement by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Federal Trade Commission, the U.S. Department of Justice and individual United States Attorney's offices within the Department of Justice, state attorneys general and state and local governments. To the extent applicable, we must comply with the fraud and abuse provisions of the Social Security Act, the federal False Claims Act, the privacy and security provisions of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended, as well as the "Anti-Kickback Law" provisions of the Social Security Act. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the Veterans Health Care Act ("VHCA"), drug companies are required to offer certain pharmaceutical products at a reduced price to a number of federal agencies, including the United States Department of Veterans Affairs and United States Department of Defense, the Public Health Service and certain private Public Health Service-designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Legislative changes have purported to require that discounted prices be offered for certain United States Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations. Furthermore, the FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. The failure to comply with laws governing international business practices may result in substantial penalties, including civil and criminal penalties.

In order to distribute products commercially, we must comply with federal and state laws and regulations that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors which ship products into the state even if such manufacturers or distributors have no place of business within the state. Federal and some state laws also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. Additionally, the federal Physician Payments Sunshine Act and implementing regulations promulgated pursuant to Section 6002 of the healthcare reform law requires the tracking and reporting of certain transfers of value made to U.S. physicians and/or certain teaching hospitals as well as ownership by a physician or a physician's family member in a pharmaceutical manufacturer. Finally, all of our activities are potentially subject to federal and state consumer protection and unfair competition laws. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and federal authorities.

On August 6, 2020, the President of the United States issued the Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States (Executive Order 13944), which required the U.S. government to purchase "essential" medicines and medical supplies produced domestically, rather than abroad. Subsequently, on October 30, 2020 the FDA published a list of essential medicines, medical countermeasures, and critical inputs as required by Executive Order. The FDA has identified around 227 drugs and 96 devices, along with their respective critical inputs or active ingredients, that the FDA believes "are medically necessary to have available at all times" for the public health. Agencies across the federal government are expected to implement the "Buy American" priorities of the Executive Order through initiation of procurement strategies to help strengthen U.S. manufacturing capabilities and focus their efforts and attention on mobilizing domestic production of these specific items. This includes the FDA accelerating approval and clearance of domestically produced medicines and countermeasures, and it may also include contract awards to specific vendors to speed up domestic production. Rabies immune globulin, such as KEDRAB, is included in the list, and given that KEDRAB is manufactured outside the United States, implementation of the "Buy American" priorities of the Executive Order may affect our ability to continue selling the product to governmental agencies in the U.S. market or otherwise require us to invest in acquiring manufacturing capabilities for the product in the U.S., either directly or through contract manufacturing arrangements. The full effect of the implementation of the Executive Order on our commercial operations and results of operations cannot be currently estimated.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. For example, in the European Union, a clinical trial application ("CTA") must be submitted to each member state's national health authority and an independent ethics committee. The CTA must be approved by both the national health authority and the independent ethics committee prior to the commencement of a clinical trial in the member state. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. In addition, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. In all cases, clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain marketing approval of a drug under European Union regulatory systems, we may submit marketing authorization applications either under a centralized, decentralized or national procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of certain diseases, and optional for those products that are highly innovative or for which a centralized process is in the interest of patients. For our products and product candidates that have received or will receive orphan designation in the European Union, they will qualify for this centralized procedure, under which each product's marketing authorization application will be submitted to the EMA. Under the centralized procedure in the European Union, the maximum time frame for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Scientific Advice Working Party of the Committee of Medicinal Products for Human Use ("CHMP")). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria: the seriousness of the disease, such as heavy disabling or life-threatening diseases, to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure provides possibility for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state, known as the reference member state. Under this procedure, an applicant submits an application, or dossier, and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America, Asia and Israel, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the coverage and reimbursement decisions made by payors. In the United States, third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Several significant laws have been enacted in the United States which affect the pharmaceutical industry and additional federal and state laws have been proposed in recent years. For example, as a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), a Medicare prescription drug benefit (Medicare Part D) became effective at the beginning of 2006. Medicare is the federal health insurance program for people who are 65 or older, certain younger people with disabilities, and people with End-Stage Renal Disease. Medicare coverage and reimbursement for some of the costs of prescription drugs may increase demand for any products for which we receive FDA approval. However, we would be required to sell products to Medicare beneficiaries through entities called "prescription drug plans," which will likely seek to negotiate discounted prices for our products.

Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation and regulation could further limit payments for pharmaceuticals such as the product candidates that we are developing. In addition, court decisions have the potential to affect coverage and reimbursement for prescription drugs. It is unclear whether future legislation, regulations or court decisions will affect the demand for our product candidates once commercialized.

As another example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Healthcare and Education Reconciliation Act of 2010 (collectively referred to as the "health care reform law"). The health care reform law made significant changes to the United States healthcare system, such as imposing new requirements on health insurers, expanding the number of individuals covered by health insurance, modifying healthcare reimbursement and delivery systems, and establishing new requirements designed to prevent fraud and abuse. In addition, provisions in the health care reform law promote the development of new payment and healthcare delivery systems, such as the Medicare Shared Savings Program, bundled payment initiatives and the Medicare pay for performance initiatives.

The health care reform law and the related regulations, guidance and court decisions have had, and will continue to have, a significant impact on the pharmaceutical industry. In addition to the general reforms briefly described above, provisions of the health care reform law directly address drugs. For example, the health care reform law:

- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- requires Medicaid rebates for covered outpatient drugs to be extended to Medicaid managed care organizations;
- requires manufacturers of drugs covered under Medicare Part D to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible Medicare beneficiaries during their coverage gap period; and
- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

On April 1, 2016, final regulations issued by the Centers for Medicare and Medicaid Services to implement the changes to the Medicaid Drug Rebate Program under the healthcare reform law became effective.

Some provisions of the healthcare reform law have yet to be fully implemented, and President Donald Trump has vowed to repeal the healthcare reform law. On January 20, 2017, President Donald Trump signed an executive order stating that the administration intended to seek prompt repeal of the healthcare reform law, and, pending repeal, directed by the U.S. Department of Health and Human Services and other executive departments and agencies to take all steps necessary to limit any fiscal or regulatory burdens of the healthcare reform law. On October 12, 2017, President Trump signed another Executive Order directing certain federal agencies to propose regulations or guidelines to permit small businesses to form association health plans, expand the availability of short-term, limited duration insurance, and expand the use of health reimbursement arrangements, which may circumvent some of the requirements for health insurance mandated by the healthcare reform law. The U.S. Congress has also made several attempts to repeal or modify the healthcare reform law. In addition, there is ongoing litigation regarding the implementation and constitutionality of the healthcare reform law. While the law is still in effect pending the ultimate resolution of the litigation, the outcome of the litigation is unknown and cannot be predicted. It is uncertain whether new legislation will be enacted to replace the healthcare reform law and whether any such legislation would affect coverage and reimbursement for prescription drugs or otherwise include provisions intended to limit the growth of healthcare costs.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure of healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any drug candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Intellectual Property

Our success depends, at least in part, on our ability to protect our proprietary technology and intellectual property, and to operate without infringing or violating the proprietary rights of others. We rely on a combination of patent, trademark, trade secret and copyright laws, know-how, intellectual property licenses and other contractual rights (including confidentiality and invention assignment agreements) to protect our intellectual property rights.

Patents

As of December 31, 2020, we owned for use within our field of business eleven families of patents and patent applications, all of which are granted or pending, respectively, in the United States, most were also filed in Europe, Canada and Israel and some were additionally filed in Russia, Turkey, certain Latin American countries, Australia and other countries, two pending PCT applications and four US provisional applications. At present, one patent family protecting our manufacturing process of GLASSIA is considered to be material to the operation of our business as a whole. Such patent has been issued in a variety of jurisdictions, including Australia, Austria, Belgium, Canada, Denmark, Estonia, Israel, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Slovenia, Poland, Spain, Portugal, Sweden, Switzerland, Turkey, the United Kingdom and the United States, and is due to expire in 2024. Furthermore, we own a patent family filed in 2018, protecting our manufacturing process of immunoglobulins. This patent family includes pending applications in the U.S., Canada, Europe and Israel.

Our patents generally relate to the separation and purification of proteins and their respective pharmaceutical compositions. Our patents and patent applications further relate to the use of our products for a variety of clinical indications, and their delivery methods. Our patents and patent applications are expected to expire at various dates between 2024 and 2040. We also rely on trade secrets to protect certain aspects of our separation and purification technology.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or any patent applications that we license will result in the issuance of any patents and there is no guarantee that patent applications that were filed with the patent offices, which are still pending, will be eventually granted and will be registered. Additionally, our issued patents and those that may be issued in the future may be challenged, opposed, narrowed, circumvented or found to be invalid or unenforceable, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. We cannot be certain that we were the first to file the inventions claimed in our owned patents or patent applications. In addition, our competitors or other third parties may independently develop similar technologies that do not fall within the scope of the technology protected under our patents, or duplicate any technology developed by us, and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for research and development, testing and regulatory review of a potential product until authorization for marketing, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Trademarks

We rely on trade names, trademarks and service marks to protect our name brands. Our registered trademarks in several countries, such as United States and the European Union, Israel, and certain Latin American countries, include the trademarks GLASSIA, RESPIKAM, KAMRAB, KEDRAB, KAMADA RESPIRA, KamRHO-D, KamRHO, KAMADA and Rebinolin.

Trade Secrets and Confidential Information

We rely on, among other things, confidentiality and invention assignment agreements to protect our proprietary know-how and other intellectual property that may not be patentable, or that we believe is best protected by means that do not require public disclosure. For example, we require our employees, consultants and service providers to execute confidentiality agreements in connection with their engagement with us. Under such agreement, they are required, during the term of the commercial relationship with us and thereafter, to disclose and assign to us inventions conceived in connection with their services to us. However, there can be no assurance that these agreements will be fulfilled or shall be enforceable, or that these agreements will provide us with adequate protection. See "Item 3. Key Information — D. Risk Factors — In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how."

We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For a more comprehensive summary of the risks related to our intellectual property, see "Item 3. Key Information — D. Risk Factors."

Property

Our production plant was built on land that Kamada Assets (2001) Ltd. ("Kamada Assets"), our 74%-owned subsidiary, leases from the Israel Land Administration pursuant to a capitalized long-term lease. Kamada Assets subleases the property to us. The property covers an area of approximately 16,880 square meters. The initial sublease expires in 2058 and we have an option to extend the sublease for an additional term of 49 years. The production plant includes our manufacturing facility, manufacturing support systems, packaging, warehousing and logistics areas, laboratory facilities and an area for the manufacture of snake bite anti-serum, as well as office buildings.

Since January 2017, we have leased approximately 2,200 square meters of a building located in the Kiryat Weizmann Science Park in Rehovot, Israel, which replaced our former Ness Ziona premises. This property houses our head office, our research and development laboratory and additional departments such as our research and development, clinical, medical, regulatory and business development departments. We sublease approximately 500 square meters of such premises to a third-party renter.

Environmental

We believe that our operations comply in material respects with applicable laws and regulations concerning the environment. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our earnings or competitive position.

Organizational Structure

Our significant subsidiaries are set forth below. All subsidiaries are either 100 percent owned by us or controlled by us. All companies are incorporated and registered in the country in which they operate as listed below:

Legal Name	Jurisdiction
Kamada Biopharma Limited	England and Wales
Kamada Inc.	Delaware
Kamada Plasma LLC	Delaware (wholly owned by Kamada Inc)
Kamada Assets (2001) Ltd.	Israel
Kamada Ireland Limited	Ireland

Legal Proceedings

We are subject to various claims and legal actions during the ordinary course of our business. We believe that there are currently no claims or legal actions that would have a material adverse effect on our financial position, operations or potential performance.

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

The following discussion of our financial condition and results of operations should be read in conjunction with "Item 3. Key Information—A. Selected Financial Data" and our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report. In addition to historical consolidated financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Item 3. Key Information—D. Risk Factors" and elsewhere in this Annual Report.

The audited consolidated financial statements for the years ended December 31, 2020, 2019 and 2018 in this Annual Report have been prepared in accordance with IFRS as issued by the IASB. None of the financial information in this Annual Report has been prepared in accordance with U.S. GAAP.

Overview

We are a global specialty plasma-derived biopharmaceutical company with a diverse portfolio of marketed products, a robust development pipeline and industry-leading manufacturing capabilities. Our strategy is focused on driving profitable growth from our current commercial activities and our plasma-derived product development and manufacturing expertise. We operate in two segments: the Proprietary Products segment, in which we use our proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to manufacture, in our cGMP compliant, FDA-approved production facility located in Beit Kama, Israel, six plasma-derived biopharmaceutical products that we market in more than 20 countries, including our two leading products GLASSIA and KEDRAB; and the Distribution segment, in which we leverage our expertise and presence in the Israeli market by distributing more than 20 pharmaceutical products manufactured by third-parties for use in Israel.

Our Products and Commercial Activities

GLASSIA was the first liquid, ready-to-use, intravenous plasma-derived AAT product approved by the FDA. GLASSIA is an intravenous AAT product that is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to AATD, and is also approved for self-administration. We market GLASSIA through a strategic partnership with Takeda in the United States. Our 2020 revenues from the sale of GLASSIA to Takeda totaled $64.9 million, as compared to $68.1 million and $63.3 million during 2019 and 2018, respectively. Based on our exclusive manufacturing, supply and distribution agreement with Takeda, we project that total revenues from sales of GLASSIA to Takeda during 2021 will be approximately $25 million, which is Takeda's minimum commitment for 2021 pursuant to our existing supply agreement. Based on the licensing and technology transfer agreement between the parties, Takeda is planning to complete the technology transfer of GLASSIA, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021. Accordingly, based on the agreement between the companies, upon initiation of sales of GLASSIA manufactured by Takeda, it will pay royalties to us at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually for each of the years from 2022 to 2040. While the transition to royalties phase will result in a reduction of our revenue from Takeda, we project, based on current GLASSIA sales in the U.S. and forecasted future growth, to receive royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040.

We also market GLASSIA in other counties through local distributors. Total revenues derived from sales of GLASSIA in all other countries during 2020 was $5.5 million, as compared to $5.5 million and $5.0 million during 2019 and 2018, respectively.

KamRAB, a hyper-immune plasma-derived therapeutic for prophylactic treatment against rabies infection administered to patients after exposure to a suspected rabid animal, is manufactured by us from plasma that contains high levels of antibodies from donors that have been previously vaccinated by an active rabies vaccine. KamRAB has been sold by us in various markets outside the United States through local distributors since 2003. In July 2011, we signed a strategic distribution and supply agreement with Kedrion for the clinical development and marketing in the United States of KamRAB, and in August 2017 we received FDA approval for anti-rabies immunoglobulin as a post-exposure prophylaxis against rabies infection. In April 2018, we launched KamRAB in the United States, under the trademark "KEDRAB." Our overall revenues from sales of KEDRAB to Kedrion during 2020, 2019 and 2018 were $18.3 million, $16.4 million and $11.8 million, respectively. Sales of KEDRAB by Kedrion in the United States during the year 2020, 2019 and 2018 totaled $23.7 million, $31.4 million and $15.5 million, respectively. Based on information provided by Kedrion, these sales represent approximately 23%, 20% and 10% share of the relevant U.S. market in each of these years, respectively. The decrease in sales of KEDRAB by Kedrion during 2020 is attributable to the impact of the COVID-19 pandemic and resulted in higher than planned inventory levels at Kedrion as of December 31, 2020.

In addition to GLASSIA and KEDRAB (and KamRAB), we manufacture two variations of a plasma-derived Anti-D product (IM for prophylaxis of hemolytic disease of newborns and IV for the treatment of immune thermobocytopunic purpura), which are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America and Asia, as well as two types of anti-snake venom derived from equine plasma, which are sold to the IMOH**.**

We intend to leverage our experience and available manufacturing capacity at our FDA-approved manufacturing facility to initiate the production of additional plasma-derived products following the transition of GLASSIA manufacturing to Takeda during 2021, through acquisitions or provision of CMO services. In line with this strategy, in December 2019, we entered into a binding term sheet for a 12-year contract manufacturing agreement with an undisclosed partner to manufacture an FDA-approved and commercialized specialty hyper-immune globulin product. Following the completion of currently on-going technology transfer process from the current manufacturer, and pending receipt of all required FDA approvals, we expect to commence commercial manufacturing of the product in early 2023. Based on the current market sales volume of this specialty hyper-immune globulin product, we estimate that its manufacturing opportunity will add approximately $8 million to $10 million to our annual revenues, with estimated gross margin level similar to the average gross margins of our Proprietary Products segment.

Our Distribution segment is comprised of sales in Israel of pharmaceutical products manufactured by third parties. Most of the revenues generated in our Distribution segment are from products produced from plasma or plasma-derivatives, and are manufactured by European companies, and its sales represented approximately 19%, 14% and 12% of our total revenues for the years ended December 31, 2020, 2019 and 2018, respectively. Over the past several years we continued to extend our Distribution segment products portfolio to non-plasma derived products, including recently entering into agreement with Alvotech and two additional entities for the distribution in Israel of nine different biosimilar products which, subject to EMA and subsequently IMOH approvals, are expected to be launched in Israel between the years 2022 and 2025. We estimate the potential aggregate maximum revenues, achievable within several years of launch, generated by the distribution of all nine biosimilar products to be in the range of $25 million to $35 million annually.

Segment performance is evaluated based on revenues and gross profit (loss). Items that are not allocated to our segments consist mainly of research and development costs, sales and marketing expenses, general and administrative costs, financial expenses, net and tax on income, each of which are managed on a group basis. For the year ended December 31, 2020, we derived $100.9 million of revenues from our Proprietary Products segment, or 76% of total revenues, and $32.3 million of revenues from our Distribution segment, or 24% of total revenues. For the year ended December 31, 2019, we derived $97.7 million of revenues from our Proprietary Products segment, or 77% of total revenues, and $29.5 million of revenues from our Distribution segment, or 23% of total revenues. For the year ended December 31, 2018, we derived $90.8 million of revenues from our Proprietary Products segment, or 79% of total revenues, and $23.7 million of revenues from our Distribution segment, or 21% of total revenues.

The transition of Glassia manufacturing to Takeda during 2021 (as discussed above) and the continued uncertainty in the operating environment created by the ongoing global COVID-19 pandemic (as described below under "COVID-19 Pandemic Effects"), as well as the continued change in product sales mix during 2021 and reduced plant utilization are anticipated to result in reduced revenues and profitability in 2021.

In addition to our commercial operations, we invest in research and development of new product candidates and new indication for existing products activities. Our two leading investigational product candidates are Anti-SARS-CoV-2 IgG as a potential treatment for COVID-19 and Inhaled AAT for AATD. For our Anti-SARS-CoV-2 IgG, we previously reported the completion of enrollment and positive interim results from our Phase 1/2 open-label, single-arm, multi-center clinical trial. We are currently assembling the final study report and plan to publish final results before the end of the first quarter of 2021. In addition, we executed an agreement with the IMOH to supply the product for the treatment of COVID-19 patients in Israel, and recently initiated the supply of the product. The initial order is sufficient to treat approximately 500 hospitalized patients and is expected to generate approximately $3.4 million in revenue in 2021. The IMOH has initiated a multi-center clinical study through which our product is being administered. In April 2020, we entered into a binding term sheet with Kedrion for the co-development, manufacturing and distribution of our human plasma-derived Anti-SARS-CoV-2 IgG product as a potential treatment for coronavirus patients. For Inhaled AAT for AATD, we are currently conducting the InnovAATe clinical trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial.

COVID-19 Pandemic Effects

The COVID-19 pandemic and the resulting measures implemented in response to the pandemic are adversely affecting, and is expected to continue to adversely affect, a number of our business activities (including our research and development, clinical trials, operations, supply chains, distribution systems, product development and sales activities) as well as those of our suppliers, customers, third-party payers and patients. Due to the impact of the pandemic and these measures, we have experienced, and expect to continue to experience, unpredictable reductions in demand for certain of our products. As a consequence, we have taken several actions to ensure our manufacturing plant remains operational with limited disruption to business continuity. We have increased inventory levels of raw materials through our suppliers and service providers, have taken measures to ensure international deliveries and shipments and have taken action to reduce certain costs and activities throughout our business operations. We are complying with the State of Israel mandates and recommendations with respect to our work-force management and currently maintain the work-force levels required to support our ongoing commercial operations. We have taken a number of precautionary health and safety measures to safeguard our employees and continue to monitor and assess orders issued by the State of Israel and other applicable governments to ensure compliance with evolving COVID-19 guidelines. While we initiated the development program of our Anti-SARS-CoV-2 IgG therapy for COVID-19, the COVID-19 pandemic affected some of our other research and development programs, including patient recruitment rate into our pivotal Phase 3 InnovAAT clinical trial, resulting in certain delays. The outbreak and preventative or protective actions that governments, corporations, individuals or we have taken or may take in the future to contain the spread of COVID-19 may result in a period of reduced operations, reduced product demand or limit the ability of customers to perform their obligations to us, delays in clinical trials or other research and development efforts, business disruption for us and our suppliers, customers and other third parties with which we do business and potential delays or disruptions related to regulatory approvals.

While COVID-19 related disruption had various effects on our business activities, commercial operation, revenues and operational expenses, as a result of the actions we have taken to date, our overall results of operations for the year ended December 31, 2020 were not materially affected; however, a number of factors, including but not limited to, continued effect of the factors mentioned above as well as, continued demand for our products, including GLASSIA and KEDRAB, in the U.S. market and our distributed products in Israel, financial conditions of our customers, suppliers and services providers, our ability to manage operating expenses, additional competition in the markets that we compete, regulatory delays, prevailing market conditions and the impact of general economic, industry or political conditions in the U.S., Israel or otherwise, may have an effect on our future financial position and results of operations.

The financial impact of these factors cannot be reasonably estimated at this time but may materially affect our business, financial condition, and results of operation. The full extent to which the pandemic impacts our business, and financial results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and duration of the pandemic and actions to contain its spread or treat its impact, among others.

Key Components of Our Results of Operations

Revenues

In our Proprietary Products segment, we generate revenues from the sale of products to strategic partners and distributors, as well as from the licensing of our technology. Revenues from our Proprietary Products segments also include a recognized portion of prior upfront and milestone payments from strategic partners. Revenues are presented net of any discounts and/or marketing contribution payments extended to our partners and distributors.

We derived a significant portion of our total revenues from sales of GLASSIA to Takeda. Sales to Takeda accounted for approximately 49%, 54% and 56% of our total revenues in the years ended December 31, 2020, 2019 and 2018, respectively. Revenue from all sales of GLASSIA comprised approximately 53%, 58% and 60% of our total revenues for the years ended December 31, 2020, 2019 and 2018, respectively. Sales of KEDRAB to Kedrion during the years ended December 31, 2020, 2019 and 2018 accounted for approximately 14%, 13% and 10% of our total revenues, respectively.

In our Distribution segment, we generate revenues from the sale in Israel of imported products produced by third parties. Sales of IVIG accounted for approximately 19%, 14% and 12% of our total revenues for the years ended December 31, 2020, 2019 and 2018, respectively.

We derived approximately 64%, 66% and 66% of our total revenues in the years ended December 31, 2020, 2019 and 2018, respectively, from sales in the United States, approximately 27%, 25% and 25% of our total revenues in the years ended December 31, 2020, 2019 and 2018, respectively, from sales in Israel (including both sales for our Proprietary Products segment and the Distribution segment), approximately 3%, 4% and 3% of our total revenues in the years ended December 31, 2020, 2019 and 2018, respectively, from sales in Europe, approximately 1%, 2% and 3% of our total revenues in the years ended December 31, 2020, 2019 and 2018, respectively, from sales in Asia (excluding Israel), and approximately 5%, 3% and 3% of our total revenues in the years ended December 31, 2020, 2019 and 2018, respectively, from sales in Latin America.

Cost of Revenues

Cost of revenues in our Proprietary Products segment includes expenses related to the manufacturing of products such as raw materials, payroll, utilities, laboratory costs and depreciation. Cost of revenues also includes provisions for the costs associated with manufacturing scraps and inventory write-offs.

A significant portion of our manufacturing costs are for raw materials consisting of plasma or fraction IV of plasma. In order to ensure the availability of plasma and fraction IV, we have secured the supply of plasma and fraction IV from multiple suppliers, including from Takeda for the manufacturing of GLASSIA and from Kedrion for the manufacturing of KEDRAB and our Anti-SARS-CoV-2 IgG product. In addition, during January 2021 we entered into an agreement for the acquisition, subject to customary closing conditions, of the plasma collection center of B&PR based in Beaumont, Texas, which specializes in the collection of hyper-immune plasma used in the manufacture of Anti-D products. The acquisition of B&PR's plasma collection center shall represent our entry into the U.S. plasma collection market and further our strategic goal of becoming a fully integrated specialty plasma company. We plan to significantly expand our hyperimmune plasma collection capacity by investing in this plasma collection center in Beaumont, Texas, and leveraging its FDA license to open additional centers in the United States. We are committed to growing our hyperimmune IgG portfolio, and believe this acquisition is a significant strategic step in that direction.

Costs of revenues in our Distribution segment consists of costs of products acquired, packaging and labeling for sales by us in Israel.

Gross Profit

Gross profit is the difference between total revenues and the cost of revenues. Gross profit is mainly affected by volume and mix of sales, as well as manufacturing efficiencies, cost of raw materials and plant maintenance and overhead costs.

Our gross margins are generally higher in our Proprietary Products segment (43%, 46% and 42% for the years ended December 31, 2020, 2019 and 2018, respectively) than in our Distribution segment (14%, 15% and 15% for the years ended December 31, 2020, 2019 and 2018, respectively).

The reduction in gross profitability during 2020, in the Propriety Products segment was as a result of changes in product sales mix, as well as reduced plant utilization. The reduction in gross profitability in our Distribution segment during 2020 was a result of a change in product sales mix which was driven by demand changes driven by the effects of the COVID-19 pandemic.

Research and Development Expenses

The development of pharmaceutical products, including plasma-derived protein therapeutics, is characterized by significant up-front product development costs. Research and development expenses are incurred for the development of new products and newly revised processes for existing products and includes expenses for pre-clinical and clinical trials, development activities in the different fields, the advanced understanding of the mechanism of action of our products, improving existing products and processes, development work at the request of regulatory authorities and strategic partners, as well as communication with regulatory authorities related to our commercial products and clinical programs. In addition, such expenses include development materials, payroll for research and development personnel, including scientists and professionals for product registration and approval, external advisors and the allotted cost of our manufacturing facility for research and development purposes. While research and development expenses are unallocated on a segment basis, the activities generally relate to our existing or in development proprietary products.

Product development costs may fluctuate from period to period, as our product candidates proceed through various stages of development. We expect to continue to incur research and development expenses related to clinical trials, as well as other ongoing, planned or future clinical trials with regard to our product pipeline. See "Item 4. Information on the Company — Our Product Pipeline and Development Program."

In order to reduce costs related to the development and regulatory approval of new protein therapeutics, in some cases we seek to share development costs with strategic partners, such as Takeda for the required post marketing clinical trials for GLASSIA in the United States, Kedrion for the clinical trials for KEDRAB in the United States required for product approval and post marketing commitments and for the development for our Anti-SARS-CoV-2 IgG product. See "Item 4. Information on the Company — Strategic Partnerships." In addition, we seek grants from dedicated governmental funds for partial funding for development projects.

Selling and Marketing Expenses

Selling and marketing expenses principally consist of compensation for employees in sales and marketing related positions, expenditures incurred for sales incentive, advertising, marketing or promotional activities, shipping and handling costs, product liability insurance and business development activities, as well as marketing authorization fees to regulatory agencies.

General and Administrative Expenses

General and administrative expenses consist of compensation for employees in executive and administrative functions (including payroll, bonus, equity compensation and other benefits), office expenses, professional consulting services, public company related costs, directors' and officer's liability insurance and other insurance costs, legal and audit fees as well as employee welfare costs.

Financial Income

Financial income is comprised of interest income on amounts invested in bank deposits and short-term investments.

Income (expense) in respect of securities measured at fair value, net

Income (expense) in respect of securities measured at fair value, net comprised the changes in the fair value of financial assets measured at fair value through other comprehensive income.

Income (expense) in respect of currency exchange differences and derivatives instruments, net

Income (expense) in respect of currency exchange differences and derivatives instruments, net is comprised of changes on balances in currencies other than our functional currency. Changes in the fair value of derivatives instruments not designated as hedging instruments are reported to profit or loss.

Financial Expenses

Financial expenses are comprised of bank charges, changes in the time value of provisions, the portion of changes in the fair value of financial assets or liabilities at fair value through other comprehensive income and interest and amortization of bank loans and leases.

Taxes on Income

Since our inception we accrued significant net operating loss carryforwards for tax purposes and as result, have not been required to pay income taxes other than tax withheld in a foreign jurisdiction in 2012 and 2016 and a $1.3 million payment to the Israel Tax Authority in 2016 as a settlement agreement for the tax years 2004-2006. In 2018, we initially recognized a deferred tax asset for a portion of our carryforward losses and during the years ended December 31, 2020 and 2019, we recognized a tax expense for the entire deferred tax asset on account of earnings that were offset against the carryforward losses.

As of December 31, 2020, we have net operating loss carryforwards for tax purposes of approximately $27.2 million. The net operating loss carryforwards have no expiration date. Following the full utilization of our net operating loss carryforwards, we expect that our effective income tax rate in Israel will reflect the tax benefits discussed below.

Our Israeli based manufacturing facility has Approved Enterprise status granted by the Israel Investment Center under the Investment Law, which made us eligible for a grant and certain tax benefits under that law for a certain investment program. The investment program provided us with a grant in the amount of 24% of our approved investments, in addition to certain tax benefits, which applied to the turnover resulting from the operation of such investment program, for a period of up to ten consecutive years from the first year in which we generated taxable income. The tax benefits under the Approved Enterprise status expired at the end of 2017. Additionally, we have obtained a tax ruling from the Israel Tax Authority according to which, among other things, our activity has been qualified as an "industrial activity," as defined in the Investment Law, and is also eligible for tax benefits as a Privileged Enterprise, which apply to the turnover attributed to such enterprise, for a period of up to ten years from the first year in which we generated taxable income. The tax benefits under the Privileged Enterprise status are scheduled to expire at the end of 2023. As of the date of this Annual Report, we have not utilized any tax benefits under the Investment Law, other than the receipt of grants attributable to our Approved Enterprise status.

We may be subject to withholding taxes for payments we receive from foreign countries. If certain conditions are met, these taxes may be credited against future tax liabilities under tax treaties and Israeli tax laws. However, due to our net operating loss carryforward, it is uncertain whether we will be able to receive such credit and therefore, we may incur tax expenses.

As we further expand our sales into other countries, we could become subject to taxation based on such country's statutory rates and our effective tax rate could fluctuate accordingly.

Results of Operations

The following table sets forth certain statement of operations data:

	Year Ended December 31,		
	2020	**2019**	**2018**
	(U.S. Dollars in thousands)		
Revenues from Proprietary Products segment	$ 100,916	$ 97,696	$ 90,784
Revenues from Distribution segment	32,330	29,491	23,685
Total revenues	133,246	127,187	114,469
Cost of revenues from Proprietary Products segment	57,750	52,425	52,796
Cost of revenues from Distribution segment	27,944	25,025	20,201
Total cost of revenues	85,694	77,450	72,997
Gross profit	47,552	49,737	41,472
Research and development expenses	13,609	13,059	9,747
Selling and marketing expenses	4,518	4,370	3,630
General and administrative expenses	10,139	9,194	8,525
Other expense	49	330	311
Operating income (loss)	19,237	22,784	19,259
Financial income	1,027	1,146	830
Income (expense) in respect of securities measured at fair value, net	102	(5)	(178)
Income (expense) in respect of currency exchange differences and derivatives instruments, net	(1,535)	(651)	602
Financial expense	(266)	(293)	(172)
Income (loss) before taxes on income	18,565	22,981	20,341
Taxes on income	1,425	730	(1,955)
Net income (loss)	$ 17,140	$ 22,251	$ 22,296

Year Ended December 31, 2020 Compared to Year Ended December 31, 2019

Segment Results

			Change 2020 vs. 2019	
	2020	**2019**	**Amount**	**Percent**
	(U.S. Dollars in thousands)			
Revenues:				
Proprietary Products	$ 100,916	$ 97,696	$ 3,220	3%
Distribution	32,330	29,491	2,839	10%
Total	133,246	127,187	6,059	5%
Cost of Revenues:				
Proprietary Products	57,750	52,425	5,325	10%
Distribution	27,944	25,025	2,919	12%
Total	85,694	77,450	8,244	11%
Gross Profit:				
Proprietary Products	$ 43,166	$ 45,271	$ (2,105)	(5)%
Distribution	4,386	4,466	(80)	(2)%
Total	$ 47,552	$ 49,737	$ (2,185)	(4)%

Revenues

In the year ended December 31, 2020, we generated $133.2 million of total revenues, as compared to $127.2 million in the year ended December 31, 2019, an increase of $6.0 million, or approximately 5%. This increase was primarily due to a $3.2 million increase in the Proprietary Products segment, comprised of a $4.1 million increase in sales of KamRab and other Proprietary products in ex-U.S. markets, mainly Israel, Latin America and Asia, and a $1.9 million increase in sales of KEDRAB to Kedrion, which was offset in part by a $3.2 decrease in GLASSIA sales to Takeda, and a $2.8 million increase in our Distribution segment attributed to increased sales of IVIG product.

Cost of Revenues

In the year ended December 31, 2020, we incurred $85.7 million of cost of revenues, as compared to $77.5 million in the year ended December 31, 2019, an increase of $8.2 million, or approximately 11%. The increase is mainly attributable to the increase in volume of sales and changes in sales mix.

Gross profit

Gross profit and gross margins in our Proprietary Products segment for the year ended December 31, 2020 were $43.2 and 42.8%, respectively, as compared to $45.3 and 46.3% for the year ended December 31, 2019, respectively, representing a decrease of $2.1 million and 4.7%, respectively. Such decrease is primarily attributed to the change in product sales mix and specifically the increase in sales of KamRab and other proprietary products in ex-U.S. markets, mainly Israel, Latin America and Asia, which carries relatively lower gross margins, as well as the decrease in sales of GLASSIA to Takeda. In addition, such decrease was attributable to reduced plant utilization which resulted in increase in the cost per vial sold.

Gross profit and gross margins in our Distribution segment for the year ended December 31, 2020 were $4.4 and 13.6%, respectively, as compared to $4.5 and 15.1% for the year ended December 31, 2019, respectively, representing a decrease of $0.1 million and 1.8%, respectively. Such decrease is primarily related to the increase in IVIG sales which carries relatively lower gross margins as well as other changes in product sales mix which were associated with demand changes driven by the effects of the COVID-19 pandemic.

Research and Development Expenses

In the year ended December 31, 2020, we incurred $13.6 million of research and development expenses, as compared to $13.1 million in the year ended December 31, 2019, an increase of $0.5 million, or approximately 3.8%. As a result of the impact of the COVID-19 pandemic on our pivotal Phase 3 InnovAATe clinical trial, we incurred a lower than projected increase in research and development expenses in the year ended December 31, 2020, as compared to the year ended December 31, 2019. Research and development expenses for the year ended December 31, 2020 includes a total of $1.1 million associated with the development of our Anti-SARS-CoV-2 IgG product as a potential therapy for COVID-19 patients. Such costs are net of $0.7 million receivables from the Israel Innovation Authority and Kedrion. Research and development expenses accounted for approximately 10.2% and 10.3% of total revenues for the years ended December 31, 2020 and 2019, respectively.

Set forth below are the research and development expenses associated with our major development programs in the years ended December 31, 2020 and 2019:

	Year ended December 31,	
	2020	**2019**
	(U.S. Dollars in thousands)	
Inhaled AAT	$ 3,266	$ 3,192
Anti-SARS-CoV-2	1,110	-
Recombinant AAT	426	352
Anti-Rabies	126	272
AAT IV for treatment of GvHD	-	666
AAT IV for lung transplantation rejection	-	34
Unallocated salary	6,045	5,816
Unallocated facility cost allocated to research and development	2,064	2,146
Unallocated other expenses	572	581
Total research and development expenses	$ 13,609	$ 13,059

Unallocated expenses are expenses that are not managed by project and are allocated between various tasks that are not always related to a major project. In the years ended December 31, 2020 and 2019, we incurred $6.0 million and $5.8 million, respectively, of unallocated salary expenses which represent all research and development salary expenses, $2.1 million and $2.1 million, respectively, of facility costs allocated to research and development and $0.6 million and $0.6 million, respectively, of unallocated other expenses.

Our current intentions with respect to our major development programs are described in “Business — Our Product Pipeline and Development Program”. We cannot determine with full certainty the duration and completion costs of the current or future clinical trials of our major development programs or if, when, or to what extent we will generate revenues from the commercialization and sale of any product candidates. We or our strategic partners may never succeed in achieving marketing approval for any product candidates. The duration, costs and timing of clinical trials and our major development programs will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation and whether our current or future strategic partners are committed to and make progress in programs licensed to them, if any. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. See “Item 3. Key Information — D. Risk Factors — Risk Related to Development, Regulatory Approval and Commercialization of Product Candidates.”

We will determine which programs to pursue and how much to fund each program in response to the scientific, pre-clinical and clinical outcome and results of each product candidate, as well as an assessment of each product candidate’s commercial potential. We cannot forecast with any degree of certainty which of our product candidates, if any, will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements.

Selling and Marketing Expenses

In the year ended December 31, 2020, we incurred $4.5 million of selling and marketing expenses, as compared to $4.4 million in the year ended December 31, 2019, an increase of $0.1 million, or approximately 3.4%. This increase was primarily due to the significant increase in shipping and freight costs in the wake of the COVID-19 pandemic. Selling and marketing expenses accounted for approximately 3.4% and 3.4% of total revenues for the years ended December 31, 2020 and 2019, respectively.

General and Administrative Expenses

In the year ended December 31, 2020, we incurred $10.1 million of general and administrative expenses, as compared to $9.2 million in the year ended December 31, 2019, an increase of $0.9 million, or approximately 10.3%. This increase was primarily due to an increase of $0.6 million in insurance costs, specifically directors' and officers' liability insurance costs which dramatically increased in recent years. General and administrative expenses accounted for approximately 7.6% and 7.2% of total revenues for the years ended December 31, 2020 and 2019, respectively.

Other expenses

In the years ended December 31, 2020 and 2019, we incurred $0.1 million and $0.3 million of other expenses, respectively, related to an ongoing technology transfer project performed with an external service provider, which was expected to be completed during 2020, however, due to several factors including the effect of the COVID-19 pandemic, the project was delayed.

Financial Income

In the years ended December 31, 2020 and 2019, we generated $1.0 million and $1.1 million of financial income, respectively. Financial income is primarily comprised of interest income on bank deposits and to a limited extent short-term investments.

Income (expense) in respect of securities measured at fair value, net

In the year ended December 31, 2020, we incurred $0.1 million of income in respect of securities measured at fair value, net, as compared to $5,000 of expenses in the year ended December 31, 2019. During 2020 we liquidated our securities portfolio.

Income (expense) in respect of currency exchange differences and derivatives instruments, net

In the year ended December 31, 2020, we incurred $1.5 million of expenses in respect of currency exchange differences on balances in other currencies, mainly the NIS and the Euro versus the U.S. dollar, and derivatives impact, as compared to $0.7 million in the year ended December 31, 2019.

Financial Expenses

In the year ended December 31, 2020, we incurred $0.3 million of financial expenses, as compared to $0.3 million in the year ended December 31, 2019.

Taxes on Income

In the year ended December 31, 2020, we recorded a $1.4 million tax expense, as compared to $0.7 million in the year ended December 31, 2019. Tax expenses relate primarily to the utilization of a deferred tax asset on account of earnings that were offset against our net operating loss carryforward for tax purposes.

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Segment Results

			Change 2019 vs. 2018	
	2019	2018	Amount	Percent
	(U.S. Dollars in thousands)			
Revenues:				
Proprietary Products	$ 97,696	$ 90,784	$ 6,912	8%
Distribution	29,491	23,685	5,806	25%
Total	127,187	114,469	12,718	11%
Cost of Revenues:				
Proprietary Products	52,425	52,796	(371)	(1)%
Distribution	25,025	20,201	4,824	24%
Total	77,450	72,997	4,453	6%
Gross Profit:				
Proprietary Products	$ 45,271	$ 37,988	$ 7,283	19%
Distribution	4,466	3,484	982	28%
Total	$ 49,737	$ 41,472	$ 8,265	20%

Revenues

In the year ended December 31, 2019, we generated $127.2 million of total revenues, as compared to $114.5 million in the year ended December 31, 2018, an increase of $12.7 million, or approximately 11%. This increase was primarily due to a $6.9 million increase in our Proprietary Products segment revenues, mainly due increase of sales of KEDRAB and GLASSIA in United States during 2019, and a $5.8 million increase in our Distribution segment, mainly attributable to increased sales of IVIG product.

Cost of Revenues

In the year ended December 31, 2019, we incurred $77.5 million of cost of revenues, as compared to $73.0 million in the year ended December 31, 2018, an increase of $4.4 million, or approximately 6%. The increase is mainly attributable to a $4.8 million in increase in cost of revenues in our Distribution segment, primarily due to an increase in volume of sales, offset in part by a decrease of $0.4 million in the Proprietary segment, mainly attributed to improved manufacturing efficiencies.

Gross profit

Gross profit in our Proprietary Products segment increased by $7.3 million in 2019, primarily due to the sales of GLASSIA and KEDRAB in the United States and resulting in improved products sales mix and improved manufacturing efficiencies. Gross profit in our Distribution segment increased by $1.0 million in 2019, primarily due to increased sales volume. As a percentage of total revenues, gross margin increased to 39.1 % for the year ended December 31, 2019 from 36.2% for the year ended December 31, 2018. Gross margin for the Proprietary Products segment, as a percentage of revenues from that segment, was 46.3% and 41.8% for the years ended December 31, 2019 and 2018, respectively. Gross margin for the Distribution segment, as a percentage of revenues from that segment, was 15.1% and 14.7% for the years ended December 31, 2019 and 2018, respectively. The increase in gross profit margin was primarily driven by an increase in the Proprietary Products segment revenues and high profitability of KEDRAB.

Research and Development Expenses

In the year ended December 31, 2019, we incurred $13.1 million of research and development expenses, as compared to $9.7 million in the year ended December 31, 2018, an increase of $3.4 million, or approximately 34%. This increase was primarily due to a $3.2 million increase in clinical trial expenses, mainly attributed to an increase in expenses in connection with the initiation of our pivotal Phase 3 InnovAATe clinical trial of approximately $2.8 million and costs associated with a proof-of-concept clinical trial of our IV-AAT as preemptive therapy for patients at high-risk for the development of steroid-refractory acute GvHD of approximately $0.3 million. Research and development expenses accounted for approximately 10.2% and 8.5% of total revenues for the years ended December 31, 2019 and 2018, respectively.

Set forth below are the research and development expenses associated with our major development programs in the years ended December 31, 2019 and 2018:

	Year ended December 31,	
	2019	**2018**
	(U.S. Dollars in thousands)	
Inhaled AAT	$ 3,192	$ 356
AAT IV for treatment of GvHD	666	356
Anti-Rabies	272	208
Recombinant AAT	352	223
AAT IV for lung transplantation rejection	34	194
Unallocated salary	5,816	5,823
Unallocated facility cost allocated to research and development	2,146	1,990
Unallocated other expenses	581	597
Total research and development expenses	$ 13,059	$ 9,747

Unallocated expenses are expenses that are not managed by project and are allocated between various tasks that are not always related to a major project. In the years ended December 31, 2019 and 2018, we incurred $5.8 million and $5.8 million, respectively, of unallocated salary expenses which represent all research and development salary expenses, $2.1 million and $2.0 million, respectively, of facility costs allocated to research and development and $0.6 million and $0.6 million, respectively, of unallocated other expenses.

Selling and Marketing Expenses

In the year ended December 31, 2019, we incurred $4.4 million of selling and marketing expenses, as compared to $3.6 million in the year ended December 31, 2018, an increase of $0.8 million, or approximately 20%. This increase was primarily due to a $0.4 million increase in registration and marketing fees and a $0.4 million increase in marketing and advertising expenses. Selling and marketing expenses accounted for approximately 3.43% and 3.2% of total revenues for the years ended December 31, 2019 and 2018, respectively.

General and Administrative Expenses

In the year ended December 31, 2019, we incurred $9.2 million of general and administrative expenses, as compared to $8.5 million in the year ended December 31, 2018, an increase of $0.7 million, or approximately 8%. This increase was primarily due to an increase of $0.4 million in salary and related expenses and $0.3 million in professional fees and employee welfare. General and administrative expenses accounted for approximately 7.2% and 7.4% of total revenues for the years ended December 31, 2019 and 2018, respectively.

Other expenses

In each of the years ended December 31, 2019, and 2018 we incurred $0.3 million of other expenses related to an ongoing technology transfer project performed with an external service provider that was planned to be completed during 2020.

Financial Income

In the years ended December 31, 2019 and December 31, 2018, we generated $1.1 million and $0.8 million of financial income, respectively, from our short-term investment portfolio and bank deposits.

Income (expense) in respect of securities measured at fair value, net

In the year ended December 31, 2019, we incurred $5,000 of expenses in respect of securities measured at fair value, net, as compared to $0.2 million in the year ended December 31, 2018.

Income (expense) in respect of currency exchange differences and derivatives instruments, net

In the year ended December 31, 2019, we incurred $0.6 million of expenses in respect of currency exchange differences on balances in other currencies versus the U.S. dollar and derivatives impact, as compared to income of $0.6 million in the year ended December 31, 2018.

Financial Expenses

In the year ended December 31, 2019, we incurred $0.3 million of financial expenses, as compared to $0.2 million in the year ended December 31, 2018.

Taxes on Income

In the year ended December 31, 2019, we recognized $0.7 million tax expenses. In the year ended December 31, 2018, we recognized a deferred tax asset representing a portion of carryforward losses that we estimate that we will realize in the coming years, resulting in tax income of $2.0 million for such period.

Quarterly Results of Operations

The following tables set forth unaudited quarterly consolidated statements of operations data for the four quarters of fiscal years 2020 and 2019. We have prepared the statement of operations data for each of these quarters on the same basis as the audited consolidated financial statements included elsewhere in this Annual Report and, in the opinion of management, each statement of operations includes all adjustments, consisting solely of normal recurring adjustments, necessary for the fair statement of the results of operations for these periods. This information should be read in conjunction with the audited consolidated financial statements and related notes included elsewhere in this Annual Report. These quarterly operating results are not necessarily indicative of our operating results for any future period.

	Three Months Ended							
	December 31, 2020	September 30, 2020	June 30, 2020	March 31, 2020	December 31, 2019	September 30, 2019	June 30, 2019	March 31, 2019
	(U.S. Dollars in thousands)							
Revenues from Proprietary Products	$ 23,283	$ 29,691	$ 22,625	$ 25,317	$ 25,175	$ 24,859	$ 27,281	$ 20,381
Revenues from Distribution	8,259	5,634	10,464	7,973	6,896	8,207	7,972	6,416
Total revenues	31,542	35,325	33,089	33,290	32,071	33,066	35,253	26,797
Cost of revenues from Proprietary Products	13,933	15,936	12,934	14,947	14,013	13,234	14,688	10,490
Cost of revenues from Distribution	7,444	4,568	9,040	6,892	5,969	6,968	6,965	5,123
Total cost of revenues	21,377	20,504	21,974	21,839	19,982	20,202	21,653	15,613
Gross profit	10,165	14,821	11,115	11,451	12,089	12,864	13,600	11,184
Research and development expenses	3,274	3,365	3,623	3,347	3,329	3,477	3,487	2,766
Selling and marketing expenses	1,221	1,179	1,178	940	929	1,161	1,188	1,092
General and administrative expenses	3,006	2,514	2,307	2,312	2,343	2,230	2,527	2,094
Other expense (income)	15	0	32	2	3	299	5	23
Operating income (loss)	2,649	7,763	3,975	4,850	5,485	5,697	6,393	5,209
Financial income	162	250	298	317	259	328	274	285
Financial expenses	(62)	(69)	(58)	(77)	(76)	(68)	(72)	(77)
Income (expense) in respect of securities measured at fair value, net	-	0	0	102	(2)	55	(6)	(52)
Income (expense) in respect of currency exchange differences and derivatives instruments, net	(839)	(761)	(367)	432	(148)	25	(216)	(312)
Income (loss) before taxes on income	1,910	7,183	3,848	5,624	5,518	6,037	6,373	5,053
Taxes on income	281	348	390	406	156	214	230	130
Net income (loss)	$ 1,629	$ 6,835	$ 3,458	$ 5,218	$ 5,362	$ 5,823	$ 6,143	$ 4,923

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, research and development expenses and capital expenditures. Historically, we have funded our operations primarily through cash flow from operations (including sales of our proprietary products and distribution products), payments received in connection with strategic partnerships (including milestone payments from collaboration agreements), issuances of ordinary shares (including our 2005 initial public offering and listing on the Tel Aviv Stock Exchange, our 2013 initial public offering in the United States and listing on Nasdaq, our 2017 underwritten public offering and our 2020 private placement), and the issuance of convertible debentures and warrants to purchase our ordinary shares. The balance of cash and cash equivalents and short-term investments as of December 31, 2020, 2019 and 2018 totaled 109.3 million, $73.9 million and $50.6 million, respectively. We plan to fund our future operations and strategic initiatives (See "Item 4. Information on the Company") through our financial resources, continued sales and distribution of our proprietary and distribution products, commercialization and or out-licensing of our pipeline product candidates, and to the extent required, raising additional capital through the issuance of equity or debt.

Our strategic partnership agreement with Takeda includes payments for the achievement of certain milestones. Since inception and through December 31, 2020, we received an aggregate of $40 million in payments under these agreements, and there are $5.0 million in payments under these agreements that we could potentially receive if we achieve additional milestones as set forth in such agreements. See "Item 4. Information on the Company— Strategic Partnerships — Takeda (GLASSIA)."

Our capital expenditures for the years ended December 31, 2020, 2019 and 2018 were $5.5 million, $2.3 million and $2.9 million, respectively. Our capital expenditures currently relate primarily to the maintenance and improvements of our facilities. We expect our capital expenditures to remain substantially similar in the near term as such capital expenditures are planned to be attributable mainly to the maintenance and improvements of our facilities.

We believe our current cash and cash equivalents and short-term investments will be sufficient to satisfy our liquidity requirements for the next 12 months.

Cash Flows from Operating Activities

Net cash provided by operating activities was $ 19.1 million for the year ended December 31, 2020. This net cash provided by operating activities reflects net income of $17.1 million, $8.1 million of non-cash expenses and a decrease in inventories of $1.2 million, a decrease in trade receivables of $1.3 million and a decrease in trade payables of $9.5 million.

Net cash provided by operating activities was $ 27.6 million for the year ended December 31, 2019. This net cash provided by operating activities reflects net income of $22.3 million, $6.3 million of non-cash expenses and an increase in inventories of $14.0 million, a decrease in trade receivables of $5.1 million and an increase in trade payables of $6.3 million.

Net cash provided by operating activities was $ 10.5 million for the year ended December 31, 2018. This net cash provided by operating activities reflects a net income of $22.3 million and non-cash expenses of $1.7 million and an increase in inventory of $8.2 million.

Cash Flows from Investing Activities

Net cash used in investing activities was $13.1 million for the year ended December 31, 2020, which comprises of investment in short term investment and bank deposits of $7.6 million and purchase of property, plant and equipment of $5.5 million.

Net cash used in investing activities was $0.6 million for the year ended December 31, 2019, which comprises of proceeds from short term investment of $1.7 million and purchase of property, plant and equipment of $2.3 million.

Net cash used in investing activities was $5.2 million for the year ended December 31, 2018. This net cash used in investing activities reflects $2.3 million net cash invested in short-term investments and investment in property, plant and equipment of $2.9 million.

Cash Flows from Financing Activities

Net cash provided by financing activities was $23.3 million for the year ended 2020, mainly due to proceeds from our January 2020 private placement to the FIMI Funds of an aggregate 4,166,667 ordinary shares at a price of $6.00 per share, for an aggregate $25 million gross proceeds.

Net cash used in financing activities was $1.5 million for the year ended 2019, mainly due to repayments of long-term loans and leases in the amount to $1.5 million.

Net cash used in financing activities was $0.6 million for the year ended 2018. This net cash used in financing activities reflects $0.6 million repayments of long-term loans.

Contractual Obligations and Commitments

The following is a summary of our contractual obligations and commitments as of December 31, 2020 (in thousands):

	Total	Less than 1 Year	1 – 3 Years	4-5 Years	More than 5 Years
	(U.S. Dollars in thousands)				
Purchase commitments	24,563	21,669	2,894	-	-
Long-term debt obligations (1)	281	244	37	-	-
Leases obligations	5,230	1,238	1,808	1,436	748
Total	30,074	23,151	4,739	1,436	748

(1) Includes interest payments on our long-term loans which bear annually fixed interest rate in the range of 3.15%-3.55%.

Purchase commitments are obligations under purchase agreements or purchase orders not yet fulfilled that are non-cancelable. Operating leases consist of contractual obligations from offices and vehicles leases agreements.

We are also obligated to make certain severance or pension payments to our Israeli employees upon their retirement under Israeli law. Due to the uncertainty of the timing of future cash flows associated with these payments (see Note 2u and Note 16 in our consolidated financial statements included in this Annual Report), we are unable to make reasonably reliable estimates for the period of cash settlement, if any, with respect to such obligations.

Seasonality

We have experienced in the past, and expect to continue to experience, certain fluctuations in our quarterly revenues. See “Item 5. Operating and Financial Review and Prospects - Quarterly Results of Operations”.

Off-Balance Sheet Arrangements

As of December 31, 2020, we have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with IFRS as issued by the IASB. The preparation of these financial statements requires management to make estimates that affect the reported amounts of our assets, liabilities, revenues and expenses. Significant accounting policies employed by us, including the use of estimates, are presented in the notes to the consolidated financial statements included elsewhere in this Annual Report. We periodically evaluate our estimates, which are based on historical experience and on various other assumptions that management believes to be reasonable under the circumstances. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require management's subjective or complex judgments, resulting in the need for management to make estimates about the effect of matters that are inherently uncertain. If actual performance should differ from historical experience or if the underlying assumptions were to change, our financial condition and results of operations may be materially impacted. In addition, some accounting policies require significant judgment to apply complex principles of accounting to certain transactions, such as acquisitions, in determining the most appropriate accounting treatment.

A detailed description of our accounting policies is provided in Note 2 of our consolidated financial statements appearing elsewhere in this Annual Report. The following provides an overview of certain accounting policies that we believe are the most critical for understanding and evaluating our financial condition and results of operations.

Revenue Recognition

Revenues are recognized when the customer obtains control over the promised goods or services. In determining the amount of revenue from contracts with customers, we evaluate whether it is a principal or an agent in the arrangement. We are a principal when we control the promised goods or services before transferring them to the customer. In these circumstances, we recognize revenue for the gross amount of the consideration.

On the contract's inception date, we assess the goods or services promised in the contract with the customer and identify the performance obligations. Revenues are recognized at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer.

We include variable consideration, such as milestone payments or volume rebates, in the transaction price, only when it is highly probable that its inclusion will not result in a significant revenue reversal in the future when the uncertainty has been subsequently resolved. For contracts that consist of more than one performance obligation, at contract inception we allocate the contract transaction price to each performance obligation identified in the contract on a relative stand-alone selling price basis.

For most contracts, revenue recognition occurs at a point in time when control of the asset is transferred to the customer, generally on delivery of the goods. For agreements with a strategic partner, performance obligations are generally satisfied over time, given that the customer either simultaneously receives or consumes the benefits provided by us, or receives assets with no alternative use, for which we have an enforceable right to payment for performance completed to date.

With respect to our agreement with Takeda, we identified the following performance obligations in the contract: (a) the grant of a license to Takeda for distribution of GLASSIA in certain territories and the supply of predetermined minimum quantities; (b) the grant of a license to Takeda for the use our knowledge and patents, and the provision of consulting services to Takeda with respect to the transfer of technology; and (c) the supply of a predetermined quantity of GLASSIA for the purpose of clinical trials performed by Takeda.

For the Takeda agreement, when determining the transaction price we took into consideration the following elements: (a) variable consideration – certain amounts of the promised consideration in the Takeda agreement, such as milestone payments and volume rebates, are variable, and were allocated to a single performance obligation or to a distinct goods or services within it; (b) significant financing component – we concluded that certain advance payments received from Takeda provide us with the benefit of financing. Therefore, we adjusted the transaction price for the effects of the time value of money; and (c) non-cash consideration – we identified raw materials provided by Takeda as non-cash consideration. This consideration is measured at fair value. We allocate the transaction price to the different performance obligation identified. This allocation is based on relative stand-alone selling price. We also concluded that we transfer the goods and services over time. This is because Takeda either receives and consumes the benefits provided by us as it is being performed, or because our performance creates assets with no alternative use and we have an enforceable right to payment for performance completed to date.

Clinical Trial Accruals and Related Expenses

We incurred costs for clinical trial activities performed by third parties (or CROs), based upon estimates made as of the reporting date of the work completed over the life of the respective study in accordance with agreements established with the CRO. We determine the estimates of clinical activities incurred at the end of each reporting period through discussion with internal personnel and outside service providers as to the progress or stage of completion of trials or services, as of the end of each reporting period, pursuant to contracts with numerous clinical trial centers and CROs and the agreed upon fee to be paid for such services.

To date, we have not experienced significant changes in our estimates of clinical trial accruals after a reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials.

Inventories

Inventories are measured at the lower of cost and net realizable value. The cost of inventories is comprised of costs required to purchase raw materials and other indirect costs required to manufacture the product (including salaries), in addition, such costs may include the costs of purchase and shipping and handling. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated selling costs.

We determine a standard manufacturing capacity for each quarter. To the extent the actual manufacturing capacity in a given quarter is lower than the predetermined standard, then a portion of the indirect costs which is equal to the product of the overall quarterly indirect costs multiplied by the quarterly manufacturing shortfall rate is recognized as costs of revenues.

We periodically evaluate the condition and age of inventories and make provisions for slow-moving inventories accordingly. Unfavorable changes in market conditions may result in a need for additional inventory reserves that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins when we sell products.

We periodically assess the potential effect on inventory in cases of deviations from quality standards in the manufacturing process to identify potential required inventory write offs. Such assessment is subject to our professional judgment.

Inventory that is produced following a change in manufacturing process prior to final approval of regulatory authorities is subject to our estimates as to the probability of receipt of such approval. We periodically reassess the probability of such approval and the remaining shelf life of such inventory. If regulatory approval is not granted, the cost of this inventory will be charged to research and development expenses.

Impairment of Non-financial Assets

We evaluate the need to record an impairment of the carrying amount of non-financial assets whenever events or changes in circumstances indicate that the carrying amount is not recoverable. If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount. The recoverable amount is the higher of fair value less costs of sale and value in use. In measuring value in use, the expected future cash flows are discounted using a pre-tax discount rate that reflects the risks specific to the asset. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs. Impairment losses are recognized in profit or loss.

An impairment loss of an asset, other than goodwill, is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. Reversal of an impairment loss, as above, will not be increased above the lower of the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years and its recoverable amount. The reversal of impairment loss of an asset presented at cost is recognized in profit or loss.

We had no impairment of non-financial assets in 2020.

Share-based Payment Transactions

Our employees and directors are entitled to remuneration in the form of equity-settled share-based payment transactions (options and restricted share units).

The cost of equity-settled transactions is measured at the fair value of the equity instruments granted at grant date. We use the binomial model when estimating the grant date fair value of equity settled share options. We selected the binomial option pricing model as the most appropriate method for determining the estimated fair value of our share-based awards without market conditions. We use the share price at the grant date when estimating the grant date fair value of equity settled restricted share units.

The determination of the grant date fair value of options using an option pricing model is affected by estimates and assumptions regarding a number of complex and subjective variables. These variables include the expected volatility of our share price over the expected term of the options, share option exercise and cancellation behaviors, expected exercise multiple, risk-free interest rates, expected dividends and the price of our ordinary shares on the TASE, which are estimated as follows:

- *Expected Life*. The expected life of the share options is based on historical data, and is not necessarily indicative of the exercise patterns of share options that may occur in the future.

- *Volatility*. The expected volatility of the share prices reflects the assumption that the historical volatility of the share prices on the TASE is reasonably indicative of expected future trends.

- *Risk-free interest rate*. The risk-free interest rate is based on the yields of non-index-linked Bank of Israel treasury bonds with maturities similar to the expected term of the options for each option group.

- *Expected forfeiture rate*. The post-vesting forfeiture rate is based on the weighted average historical forfeiture rate.

- *Dividend yield and expected dividends*. We have not recently declared or paid any cash dividends on our ordinary shares and do not intend to pay any cash dividends. We have therefore assumed a dividend yield and expected dividends of zero.

- *Share price on the TASE*. The price of our ordinary shares on the TASE used in determining the grant date fair value of options is based on the price on the grant date.

If any of the assumptions used in the binomial model change significantly, share-based compensation for future awards may differ materially compared with the awards granted previously.

The cost of equity-settled transactions is recognized in profit or loss, together with a corresponding increase in equity, during the period which the performance and/or service conditions are to be satisfied, ending on the date on which the relevant grantee become fully entitled to the award. The cumulative expense recognized for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The expense or income recognized in profit or loss represents the change between the cumulative expense recognized at the end of the reporting period and the cumulative expense recognized at the end of the previous reporting period.

No expense is recognized for awards that do not ultimately vest.

If we modify the conditions on which equity-instruments were granted, an additional expense is recognized for any modification that increases the total fair value of the share-based payment arrangement or is otherwise beneficial to the grantee at the modification date.

If a grant of an equity instrument is cancelled, it is accounted for as if it had vested on the cancellation date, and any expense not yet recognized for the grant is recognized immediately. However, if a new grant replaces the cancelled grant and is identified as a replacement grant on the grant date, the cancelled and new grants are accounted for as a modification of the original grant, as described above.

Post-employment Benefits Liabilities

Our post-retirement benefit plans are normally financed by contributions to insurance companies and classified as defined contribution plans or as defined benefit plans.

We operate a defined benefit plan in respect of severance pay pursuant to the Israeli Severance Pay Law, 1963. See Note 2u and Note 16 in our consolidated financial statements included in this Annual Report for more details.

The present value of our severance pay depends on a number of factors that are determined on an actuarial basis using a number of assumptions. The assumptions used in determining the net cost or income for severance pay and plan assets include a discount rate. Any changes in these assumptions will impact the carrying amount of severance pay and plan assets.

Other key assumptions inherent to the valuation include employee turnover, inflation, expected long term returns on plan assets and future payroll increases. The expected return on plan assets is determined by considering the expected returns available on assets underlying the current investments policy. These assumptions are given a weighted average and are based on independent actuarial advice and are updated on an annual basis. Actual circumstances may vary from these assumptions, giving rise to a different severance pay liability.

Accounting for Income Taxes

At the end of each reporting period, we are required to estimate our income taxes. There are transactions and calculations for which the ultimate tax determination is uncertain during the ordinary course of business, determined according to complex tax laws and regulations. Where the effect of these laws and regulations is unclear, we use estimates in determining the liability for the tax to be paid on our past profits, which we recognize in our financial statements. We believe the estimates, assumptions and judgments are reasonable, but this can involve complex issues which may take a number of years to resolve. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the income tax and deferred income tax provisions in the period in which such determination is made. In addition, at the end of each reporting period, we estimate our ability to utilize our carryforward losses and accordingly account for the relevant amount of deferred taxes. When calculating the deferred tax asset, we estimate the effective tax rate to be applied for the years in which we expect the carryforward loss to be utilized, considering the impact of the Israeli Law for the Encouragement of Capital Investments, 1959 (as amended) and rulings that we received from the Israel Tax Authority.

We follow IFRIC 23, "Uncertainty over Income Tax Treatments" (the "Interpretation") issued by the IASB, The Interpretation clarifies the accounting for recognition and measurement of assets or liabilities in accordance with the provisions of IAS 12, "Income Taxes", in situations of uncertainty involving income taxes. The Interpretation provides guidance on: (i) considering whether some tax treatments should be considered collectively; (ii) measurement of the effects of uncertainty involving income taxes on the financial statements; and (iii) accounting for changes in facts and circumstances in respect of the uncertainty.

As of December 31, 2020, 2019 and 2018, the application of IFRIC 23 did not have a material effect on the financial statements.

Short-term investments

Our short-term bank investments include deposits that have a maturity of more than three months from the deposit date but less than one year and financial assets measured at fair value through other comprehensive income that include debt securities. Debt financial instruments are subsequently measured at fair value through profit or loss ("FVPL"), amortized cost or fair value through other comprehensive income ("FVOCI"). The classification is based on two criteria: our business model for managing the assets; and whether the instruments' contractual cash flows represent solely payments of principal and interest on the principal amount outstanding ("SPPI").

The classification and measurement of our debt financial assets are as follows:

- Debt instruments measured at amortized cost for financial assets that are held within a business model with the objective to hold the financial assets in order to collect contractual cash flows that meet the SPPI criteria. This category includes our trade and other receivables.

- Debt instruments measured at FVOCI, with gains or losses recycled to profit or loss on the recognition. Financial assets in this category are our quoted debt instruments that meet the SPPI criteria and are held within a business model both to collect cash flows and to sell. Interest earned whilst holding available for sale financial investments is reported as interest income using the effective interest rate method.

Our policy is to record an allowance for expected credit loss ("ECL") for all debt financial assets not measured at FVPL. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and the cash flows that we actually expect to receive. For other debt financial assets (i.e., debt securities measured at FVOCI), the ECL is based on the 12-month ECL. The 12-month ECL is the portion of lifetime ECLs that results from default events on a financial instrument that are possible within 12 months after the reporting date. As of December 31, 2020, we have liquidated our securities portfolio.

Leases

As of January 1, 2019, we applied IFRS 16, "Leases". We account for a contract as a lease when the contract terms convey the right to control the use of an identified asset for a period of time in exchange for consideration.

On the inception date of the lease, we determine whether the arrangement is a lease or contains a lease, while examining if it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. In our assessment of whether an arrangement conveys the right to control the use of an identified asset, we assess whether we have the following two rights throughout the lease term:

(a) The right to obtain substantially all the economic benefits from use of the identified asset; and

(b) The right to direct the identified asset's use.

For leases in which we are the lessee, we recognize on the commencement date of the lease a right-of-use asset and a lease liability, excluding leases whose term is up to 12 months and leases for which the underlying asset is of low value. For these excluded leases, we have elected to recognize the lease payments as an expense in profit or loss on a straight-line basis over the lease term. In measuring the lease liability, we have elected to apply the practical expedient in IFRS 16 and do not separate the lease components from the non-lease components (such as management and maintenance services, etc.) included in a single contract.

On the commencement date, the lease liability includes all unpaid lease payments discounted at the interest rate implicit in the lease, if that rate can be readily determined, or otherwise using our incremental borrowing rate. After the commencement date, we measure the lease liability using the effective interest rate method.

On the commencement date, the right-of-use asset is recognized in an amount equal to the lease liability plus lease payments already made on or before the commencement date and initial direct costs incurred less any lease incentives received. The right-of-use asset is measured applying the cost model and depreciated over the shorter of its useful life or the lease term. We test for impairment of the right-of-use asset whenever there are indications of impairment pursuant to the provisions of IAS 36.

For additional information, see Note 2m, and Note 14b in our consolidated financial statements included in this Annual Report.

Government grants

We record government grants when there is reasonable assurance that the grants will be received, and we will comply with the attached conditions.

Government grants received from the Israel Innovation Authority (formerly the Office of the Chief Scientist of the Israel Ministry of Economy) are recognized upon receipt as a liability if future economic benefits are expected from the research project that will result in royalty-bearing sales.

A liability for royalties is first measured at fair value using a discount rate that reflects a market rate of interest. The difference between the amount of the grant received and the fair value of the liability is accounted for as a government grant and recognized as a reduction of research and development expenses. After initial recognition, the liability is measured at amortized cost using the effective interest method. Royalty payments are treated as a reduction of the liability. If no economic benefits are expected from the research activity, the grant receipts are recognized as a reduction of the related research and development expenses. In that event, the royalty obligation is treated as a contingent liability in accordance with IAS 37.

Item 6. Directors, Senior Management and Employees

Executive Officers and Directors

The following table sets forth certain information relating to our executive officers and directors as of February 24, 2021.

Name	Age	Position
Executive Officers:		
Amir London	52	Chief Executive Officer
Chaime Orlev	50	Chief Financial Officer
Michal Ayalon, PhD	54	Vice President, Research and Development and IP
Yael Brenner	57	Vice President, Quality
Hanni Neheman	51	Vice President, Marketing & Sales
Eran Nir	48	Vice President, Operations
Yifat Philip	44	Vice President, General Counsel and Corporate Secretary
Orit Pinchuk	55	Vice President, Regulatory Affairs and PVG
Ariella Raban	45	Vice President, Human Resources
Dr. Naveh Tov, PhD	57	Vice President, Clinical Development and Medical Director
Directors:		
Lilach Asher Topilsky*	50	Chairman of the Board of Directors
Avraham Berger*	69	Director, Chairman of Audit Committee
Amiram Boehm *	49	Director
Ishay Davidi*	58	Director
Karnit Goldwasser*	44	Director
Jonathan Hahn	38	Director, Chairman of Strategy Committee
Leon Recanati*	72	Director, Chairman of Compensation Committee
Prof. Ari Shamiss, MD*	62	Director
David Tsur	71	Director

* Independent director under the Nasdaq listing requirements.

Executive Officers

Amir London has served as our Chief Executive Officer since July 2015. Prior to that, Mr. London served as our Senior Vice President, Business Development since December 2013. Mr. London brings with him over 20 years of senior management and international business development experience. From 2011 to 2013, Mr. London served as the Chief Operating Officer of Fidelis Diagnostics, a U.S.-based provider of innovative in-office medical diagnostic services. Earlier in his career, from 2009 to 2011, Mr. London was the Chief Executive Officer of Promedico, a leading Israeli-based $350 million healthcare distribution company, and the General Manager of Cure Medical, from 2006 to 2009, providing contract manufacturing services for clinical studies, as well as home-care solutions. From 1995 to 2006, Mr. London was a Partner with Tefen, an international publicly-traded operations management consulting firm, responsible for the firm's global biopharma practice. Mr. London holds a B.Sc. degree in Industrial and Management Engineering from the Technion – Israel Institute of Technology.

Chaime Orlev has served as our Chief Financial Officer since December 2017. Prior to that, Mr. Orlev had served in senior finance roles for more than 20 years, with approximately 12 years spent in the life sciences industry. Most recently, from September 2016 to November 2017, Mr. Orlev served as Chief Financial Officer and Vice President Finance and Administration at Bioblast Pharma Ltd. (Nasdaq: ORPN), a clinical-stage, orphan disease-focused biotechnology company. Prior to that, from 2010, Mr. Orlev served as Vice President Finance and Administration at Chiasma (Nasdaq: CHMA), currently, a commercial biopharmaceutical company focused on treating rare and serious chronic diseases. In this role, Mr. Orlev helped lead the company's 2015 over $100 million initial public offering and listing on Nasdaq, and participated in the negotiations and closing of the licensing agreement for the company's lead product to F. Hoffmann-La Roche. Previously, Mr. Orlev was Chief Financial Officer at Oramed Pharmaceuticals Inc. (Nasdaq: ORMP), which has developed an innovative technology to transform injectable treatments into oral therapies. In this role, Mr. Orlev led multiple capital raises. Mr. Orlev is a certified public accountant in Israel, holds an MBA degree from the Leon Recanati Graduate School of Business Administration at the Tel Aviv University and a BA degree in Business Administration from the College of Management in Israel.

Dr. Michal Ayalon has served as our Vice President, Research and Development and IP since February 2019. Prior to joining us, from 2018 to 2019, Dr. Ayalon served as Head of R&D at 89bio Ltd., where Dr. Ayalon led the overall development strategy of the company and managed all R&D functions, including medical, clinical, pre-clinical, CMC, regulatory, and project management. Prior to that, from 2016 to 2018, Dr. Ayalon served as Project Champion at Teva Pharmaceutical Industries Ltd., where she led novel biologics and biosimilar projects in oncology, respiratory and metabolic disease. In 2015, Dr. Ayalon served as Vice President of Research & Development at Galmed Pharmaceuticals Ltd., where she led the pre-clinical as well as CMC activities and managed the clinical operation group. Prior to that, Dr. Ayalon worked for Immune Pharmaceuticals, Inc. (from 2012 to 2015), BioLineRx and Compugen Ltd. Dr. Ayalon received her B.Sc., M.Sc. and Ph.D. degrees from Tel-Aviv University, Faculty of Life Sciences. Dr. Ayalon completed her postdoctoral research at Weizmann Institute of Science in the Department of Molecular Biology of the Cell. Dr. Ayalon is the author of multiple patents and publications.

Yael Brenner has served as our Vice President, Quality since March 2015. Ms. Brenner has more than 25 years of experience in Quality Management, including Quality Assurance and Quality Control managerial positions in the pharmaceutical industry. Prior to joining Kamada, from 2007 to 2015, Ms. Brenner was at Teva Pharmaceuticals Industries, lastly as Senior Director Quality Operations of Teva Kfar Sava Site, managing over 400 employees in Quality Assurance, Quality Control and Regulatory Affairs. Ms. Brenner holds B.Sc. and M.Sc. degrees in Chemistry from the Technion - Israel Institute of Technology, and in addition is a Certified Quality Engineer (CQE) from the American and Israeli Societies for Quality.

Hanni Neheman has served as our Vice President, Marketing & Sales since January 2020. Ms. Neheman joined us in August 2014 and served as Head of Business Operations, Israel. Ms. Neheman has more than 20 years of expertise in different positions in the field of marketing and sales in the pharmaceutical industry. Prior to joining us, Ms. Neheman served as a Commercial Manager at Neopharm Israel. Ms. Neheman holds a B.A. degree in Occupational Therapy from the Technion Israel Institute of Technology and Executive M.B.A degree from Derby University.

Eran Nir has served as our Vice President, Operations since November 1, 2016. Mr. Nir has over 20 years of operations management experience in the pharmaceutical and medical industries. Mr. Nir's recent roles include management of TEVA's Pharmaceutical plant in Jerusalem from 2002 to 2011, VP Operations of Amelia Cosmetics from 2014 to 2015 and management of a medical equipment plant of Philips Medical Systems from 2015 to 2016. Mr. Nir's extensive experience spans across the management of large scale FDA and EMA- approved manufacturing facilities, tech-transfer of new products from development to production and the implementation of world-class operational excellence systems. Mr. Nir holds a B.Sc. degree in Industrial and Management Engineering and a MBA degree in Business Management, both from Ben-Gurion University.

Yifat Philip has served as our VP General Counsel and Corporate Secretary since October 2020. Ms. Philip has been practicing law for more than 15 years, with an experience of over a decade in the BioMed industry. Prior to joining Kamada, Ms. Philip served as VP Legal Affairs and Compliance Officer of OPKO Biologics, a subsidiary of OPKO Health, Inc. (NASDAQ:OPK), responsible for all the company's legal matters and commercial agreements, including IP licensing, R&D collaborations, clinical trials and drug manufacturing contracts. Ms. Philip has vast experience from leading law firms on international biotech M&A deals, joint ventures and commercial transactions. Prior to that, Ms. Philip worked at the Israel Securities Authority, the Department of Economics and Fiscal Law of the State Attorney, Israel. Ms. Philip is a member of the Israel Bar Association and holds an LLB degree (cum laude) and a BA degree in Economics, both from Haifa University; an MA degree (cum laude) in Law and Economics from Erasmus University in the Netherlands in collaboration with Berkeley University, USA; and an MBA degree from the Technion-Israel Institute of Technology, Israel. Ms. Philip also serves as a member of the board of directors of the Israeli Association of Corporate Counsels and head of the ACC BioMed Forum.

Orit Pinchuk has served as our Vice President, Regulatory Affairs and PVG since October 2014. Ms. Pinchuk has experience of more than 25 years in the pharmaceutical industry, fulfilling key positions that cover, among others, disciplines of Regulatory Affairs and Compliance. Prior to joining Kamada, Ms. Pinchuk was at Teva Pharmaceuticals Industries, from 1993 to 2014, where she served as Director of Compliance and Regulatory Affairs, Operation Israel and Senior Director Regulatory Affairs, Research and Development and Operation Israel. Ms. Pinchuk has extensive experience with FDA, EMA and Canada Health Authorities. Ms. Pinchuk holds a B.Tech degree in Textile Chemistry from Shenkar College for Engineering and Design and M.Sc. degree in Applied Chemistry from the Hebrew University of Jerusalem.

Ariella Raban has served as our Vice President, Human Resources since May 2018. Ms. Raban joined us in March 2014 and served as Human Resources Manager at our manufacturing facility in Beit Kama. Ms. Raban has experience of 14 years in different positions in the field of human resources in the pharmaceutical industry. Prior to joining us, Ms. Raban served as a Human Resources Manager at Teva Pharmaceuticals Industries Ltd. Ms. Raban holds a B.A. degree in Humanities Social Science from Ben-Gurion University.

Dr. Naveh Tov has served as our Vice President, Clinical Development and Medical Director for Pulmonary Diseases since July 2016. Prior to joining us, Dr. Tov served as our Medical Director in a part- time consultancy role, from 2007. Dr. Tov served in both active hospital academic and clinical positions at Bnei Zion Medical Center, Haifa, Israel from 1994 through 2016. Dr. Tov specializes in Internal, Pulmonary and Sleep Medicine and served as Head of the Pulmonary Unit and as Deputy of Internal Ward C at Bnei Zion Medical Center, for 14 years from 2002 through 2016. During these years, Dr. Tov served in academia and held appointments at the Ruth and Bruce Rappaport Faculty of Medicine of The Technion – Israel Institute of Technology. Dr. Tov is a member of the American Thoracic Society and the European Respiratory Society. Dr. Tov holds an M.D. and a Ph.D. from the Ruth and Bruce Rappaport Faculty of Medicine of The Technion – Israel Institute of Technology. With respect to change in Dr. Tov's terms of employment, see "*Agreements with Five Most Highly Compensated Office Holders" below*.

Directors

Mrs. Lilach Asher Topilsky has served as a member of our board of directors since December 2019, as the Chairman of our board of directors since August 2020, and serves as a member of our Compensation Committee and Strategy Committee. Mrs. Asher Topilsky has been a Senior Partner in the FIMI Opportunity Funds, Israel's largest group of private equity funds, since December 2019. Mrs. Asher Topilsky currently serves as the chairman of G1 Security Systems Ltd. (TASE), Rimoni Industries Ltd. (TASE) and Elyakim Ben Ari Group Ltd. and as a director at Amiad Water Systems Ltd. (AIM) and Tel Aviv University. Prior to joining FIMI, Mrs. Asher Topilsky served as the President and CEO of Israel Discount Bank (TASE), one of the leading banking groups in Israel, as the Chairman at IDBNY BANKCORP and as a director at IDB Bank New York from 2014 -2019. Mrs. Asher Topilsky also served as the Chairman of Mercantile Bank from 2014-2016. Before that, Mrs. Asher Topilsky served as a member of the management of Bank Hapoalim (TASE) as Deputy CEO & Head of Retail Banking Division (2009-2013) & Head of Strategy & Planning Division (2007-2009). Mrs. Asher Topilsky served as a Strategy Consultant at The Boston Consulting Group (BCG, Chicago 1997-1998) and at Shaldor Strategy Consulting (Israel 1995-1996). Mrs. Asher Topilsky holds an M.B.A. degree from Kellogg School of Management, Northwestern University, Chicago, USA (1997), and a B.A. degree in Management and Economics from Tel Aviv University, Israel (Magna Cum Laude, 1994).

Avraham Berger has served on our board of directors since August 2016, and serves as the Chair of our Audit Committee and as a member of our Compensation Committee. Until 2014, Mr. Berger served as a senior partner and Chief Executive Officer of PwC Israel, for more than 20 years. Mr. Berger joined PwC Israel in 1976 and led it from 1991. Mr. Berger has vast experience in mergers and acquisitions and complex public offerings, both in Israel and abroad. Mr. Berger lectures at professional forums and has published several articles in the professional press. Mr. Berger also serves as Chairman of the board of directors of TopAudio Ltd. and serves as director on the board of Weizmann Institute of Science. Mr. Berger holds a BA degree in Accounting and Economics from Tel Aviv University and is a certified public accountant in Israel.

Amiram Boehm has served on our board of directors since December 2019 and serves as a member of our Strategy Committee. Mr. Bohem is a Partner in the FIMI Opportunity Funds, Israel's largest group of private equity funds, since 2004. Mr. Boehm served as the Managing Partner and Chief Executive Officer of FITE GP (2004), and serves as a director at Gilat Satellite Communications (NASDAQ), Ham-Let (Israel-Canada) Ltd. (TASE), Hadera Paper Ltd (TASE)., Rekah Pharmaceuticals Ltd. (TASE), TAT Technologies Ltd. (NASDAQ, TASE), PCB Technologies Ltd. (TASE) and DelekSan Ltd. and Galam Ltd. Mr. Boehm previously served as a director of DIMAR Ltd, Ormat Technologies Inc. (NYSE, TASE), Scope Metal Trading Ltd. (TASE), Inter Industries, Ltd. (TASE), Global Wire Ltd. (TASE), Telkoor Telecom Ltd. (TASE) and Solbar Industries Ltd. (previously traded on the TASE) and Novolog Ltd (TASE). Prior to joining FIMI, from 1999 until 2004, Mr. Boehm served as Head of Research of Discount Capital Markets, the investment arm of Israel Discount Bank. Mr. Boehm holds a BA degree in Economics and LLB degree from Tel Aviv University and a Joint MBA degree from Northwestern University and Tel Aviv University.

Ishay Davidi has served on our board of directors since December 2019. Mr. Davidi is the Founder and has served as Chief Executive Officer of the FIMI Opportunity Funds, Israel's largest group of private equity funds, since 1996. Mr. Davidi currently serves as the Chairman of the Board of Directors of Hadera Paper Ltd. (TASE) and Polyram Plastic Industries Ltd (TASE). Mr. Davidi also serves as a director of Gilat Satellite Networks Ltd. (NASDAQ and TASE), Ham-Let Ltd. (TASE), Bet Shemesh Engines Ltd. (TASE), C. Mer Industries Ltd. (TASE), G1 Security Systems Ltd. (TASE), PCB Technologies Ltd. (TASE), Tadir- Gan (precision products) 1993 Ltd. (TASE), Rekah Pharmaceutical Industries (TASE), SOS Ltd., DelekSan Ltd., Amiad Water Systems Ltd (AIM), Rimoni Industries Ltd. (TASE) and Elyakim Ben-Ari Group Ltd. Mr. Davidi previously served as the Chairman of the board of directors of Inrom, Retalix (previously traded on NASDAQ and TASE) and Tefron Ltd. (NYSE and TASE) and as a director of Pharm Up Ltd (TASE), Ormat Industries Ltd. (previously traded on TASE), Lipman Electronic Engineering Ltd. (NASDAQ and TASE), Merhav Ceramic and Building Materials Center Ltd. (NASDAQ and TASE), Orian C.M. Ltd. (TASE), Ophir Optronics Ltd., Overseas Commerce Ltd, (TASE), Scope Metals Group Ltd. (TASE) and Formula Systems Ltd. (NASDAQ and TASE). Prior to establishing FIMI, from 1993 until 1996, Mr. Davidi was the Founder and Chief Executive Officer of Tikvah Fund, a private Israeli investment fund. From 1992 until 1993 Mr. Davidi served as the Chief Executive Officer of Zer Science Industries Ltd. Mr. Davidi holds an M.B.A. degree from Bar Ilan University, Israel, and a B.Sc. degree, with honors, in Industrial Engineering from the Tel Aviv University, Israel.

Karnit Goldwasser has served on our board of directors since December 2019 and serves as a member of our Audit Committee and Compensation Committee. Ms. Goldwasser serves as an independent consultant and environmental engineer for various agencies and organizations. Ms. Goldwasser is a director at Delek San Recycling Ltd. (since December 2016) and ELA Recycling Corporation (since April 2015). Ms. Goldwasser previously served as a director at Orian DB Schenker (2017-2020) and at the government-owned Environmental Services Company Ltd., as chair of the Safety Committee (2010-2016), and as a member of the Tel Aviv-Jaffa City Council, holding the environmental portfolio (2013-2016). Ms. Goldwasser also served as a director in several Tel Aviv-Jaffa municipality corporations: Dan Municipal Sanitation Association, as chair of the audit committee; Tel Aviv-Jaffa Economic Development Authority; and Ganei Yehoshua Co. Ltd. Ms. Goldwasser holds a B.Sc. degree in Environmental Engineering, focusing on chemistry, mathematics and environmental engineering, and M.Sc. degree in Civil Engineering, specializing in Hydrodynamics and Water Resources, both from the Technion – Israel Institute of Technology, and MA degree in Public Policy and Administration from the Lauder School of Government Diplomacy and Strategy, IDC Herzliya. Ms. Goldwasser also completed the Directors Program at LAHAV, School of Management, Tel Aviv University.

Jonathan Hahn has served on our board of directors since March 2010, and serves as the Chairman of our Strategy Committee. Mr. Hahn serves as the President and a director of Tuteur SACIFIA, where he has been since 2013. Prior to that, Mr. Hahn served as Strategic Planning Manager at Tuteur and held a business development position at Forest Laboratories, Inc., based in New York. Mr. Hahn holds a BA degree from San Andrés University and an MBA degree from New York University — Stern School of Business, with specializations in Finance and Entrepreneurship.

Leon Recanati has served on our board of directors since May 2005, as the Chairman of our board of directors from March 2013 to August 2020, and serves as the Chairman of our Compensation Committee. Mr. Recanati currently serves as a board member of Evogene Ltd., a plant genomics company listed on the TASE and New York Stock Exchange. Mr. Recanati is also a board member of the following private companies: GlenRock Israel Ltd., Gov, Govli Limited, RelTech Holdings Ltd., Legov Ltd., Insight Capital Ltd., and Shavit Capital Funds. Mr. Recanati currently serves as the Chairman and Chief Executive Officer of GlenRock. Previously, Mr. Recanati was Chief Executive Officer and/or Chairman of IDB Holding Corporation; Clal Industries Ltd.; Azorim Investment Development and Construction Co Ltd.; Delek Israel Fuel Corporation; and Super-Sol Ltd. Mr. Recanati also founded Clal Biotechnologies Industries Ltd., a biotechnology investment company operating in Israel. Mr. Recanati holds an MBA degree from the Hebrew University of Jerusalem and Honorary Doctorates from the Technion – Israel Institute of Technology and Tel Aviv University.

Prof. Ari Shamiss has served as on our board of directors since August 2020 and serves as a member of our Audit Committee. Prof. Shamiss is the Founder, General Partner and Chairman of the Investment Committee at Assuta Life Sciences Ventures, a life sciences-focused venture capital entity. Prior to that, from September 2016 to June 2020 he served as CEO of Assuta Medical Centers, the largest private hospital network in Israel, which includes eight hospitals and medical centers, with over $600 million in annual revenue. From July 2005 to 2016, Prof. Shamiss was the chief executive officer of Sheba General Hospital, the largest hospital in Israel. Prof. Shamiss also served as Vice Dean at Ben Gurion University School of Medicine from January 2017 to June 2020 and remains a Professor at the institution. Prof. Shamiss is a past Surgeon General of the Israel Air Force, Colonel (Retired). Prof. Shamiss currently serves on the boards of BATM Advanced Technologies and Therapix Biosciences.

David Tsur has served as on our board of directors since July 2015, as Active Deputy Chairman on a half-time basis until December 31, 2019 and serves as a member of our Strategy Committee. Prior to that, Mr. Tsur served as our Chief Executive Officer and a director since our inception. Prior to co-founding Kamada in 1990, Mr. Tsur served as Chief Executive Officer of Arad Systems and RAD Chemicals Inc. Mr. Tsur previously served as the Chairman of the Board of Directors of CollPlant Ltd., a company listed on the TASE and OTC market. Mr. Tsur has also held various positions in the Israeli Ministry of Economy and Industry (formerly named the Ministry of Industry and Trade), including Chief Economist and Commercial Attaché in Argentina and Iran. Mr. Tsur serves as the Chairman of the Board of Directors of Kanabo Ltd. (LSE). Mr. Tsur holds a BA degree in Economics and International Relations and an MBA degree in Business Management, both from the Hebrew University of Jerusalem.

Under a shareholders' agreement entered into on March 6, 2013, the Recanati Group, on the one hand, and the Damar Group, on the other hand, have each agreed to vote the ordinary shares beneficially owned by them in favor of the election of director nominees designated by the other group as follows: (i) three director nominees, so long as the other group beneficially owns at least 7.5% of our outstanding share capital, (ii) two director nominees, so long as the other group beneficially owns at least 5.0% (but less than 7.5%) of our outstanding share capital, and (iii) one director nominee, so long as the other group beneficially owns at least 2.5% (but less than 5.0%) of our outstanding share capital. In addition, to the extent that after the designation of the foregoing director nominees there are additional director vacancies, each of the Recanati Group and Damar Group have agreed to vote the ordinary shares beneficially owned by them in favor of such additional director nominees designated by the party who beneficially owns the larger voting rights in our company. See "Item 7. Major Shareholders and Related Party Transactions — Related Party Transactions — Shareholder Agreement."

Board of Directors

Under our articles of association, the number of directors on our board of directors must be no less than five and no more than 11. Our board of directors currently consists of nine directors, seven of whom qualify as "independent directors" under the Nasdaq listing requirements, such that we comply with the Nasdaq Listing Rule that requires that a majority of our board of directors be comprised of independent directors, within the meaning of Nasdaq Listing Rules.

Our directors are elected by the vote of a majority of the ordinary shares present, in person or by proxy, and voting at a shareholders' meeting. Each director holds office until the first annual general meeting of shareholders following his or her appointment, unless the tenure of such director expires earlier pursuant to the Israeli Companies Law, 1999 (the "Israeli Companies Law") or unless he or she is removed from office as described below.

Vacancies on our board of directors, including vacancies resulting from there being fewer than the maximum number of directors permitted by our articles of association, may generally be filled by a vote of a simple majority of the directors then in office.

A general meeting of our shareholders may remove a director from office prior to the expiration of his or her term in office by a resolution adopted by holders of a majority of our shares voting on the proposed removal, provided that the director being removed from office is given a reasonable opportunity to present his or her case before the general meeting.

External Directors

Under the Companies Law, companies incorporated under the laws of the State of Israel that are "public companies," must appoint at least two external directors who meet the qualification requirements in the Companies Law.

However, according to regulations promulgated under the Israel Companies Law, a company whose shares are traded on certain stock exchanges outside Israel (including the Nasdaq Global Select Market, such as our company) that does not have a controlling shareholder and that complies with the requirements of the laws of the foreign jurisdiction where the company's shares are listed, as they apply to domestic issuers, with respect to the appointment of independent directors and the composition of the audit committee and compensation committee, may elect to exempt itself from the requirements of Israeli law with respect to (i) the requirement to appoint external directors and that one external director serve on each committee of the board of directors authorized to exercise any of the powers of the board of directors; (ii) certain limitations on the employment or service of an external director or his or her spouse, children or other relatives, following the cessation of the service as an outside director, by or for the company, its controlling shareholder or an entity controlled by the controlling shareholder; (iii) the composition, meetings and quorum of the audit committee; and (iv) the composition and meetings of the compensation committee. If a company has elected to avail itself from the requirement to appoint external directors and at the time a director is appointed all members of the board of directors are of the same gender, a director of the other gender must be appointed.

On January 30, 2017, following analysis of our qualification to rely on the exemption, our board of directors determined to adopt the exemption. If in the future we were to have a controlling shareholder, we would again be required to comply with the requirements relating to external directors and the composition of the audit committee and compensation committee under Israeli law.

Audit Committee

We have an audit committee consisting of Mr. Avraham Berger, Ms. Karnit Goldwasser and Prof. Ari Shamiss. Mr. Avraham Berger serves as the chairman of the audit committee.

In accordance with regulations promulgated under the Companies Law described above, we elected to "opt out" from the Companies Law requirement to appoint external directors and related rules concerning the composition of the audit committee and compensation committee. Under such exemption, among other things, the composition of our audit committee must comply with the requirements of SEC and Nasdaq rules.

Under the Exchange Act and Nasdaq listing requirements, we are required to maintain an audit committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise. Our board of directors has affirmatively determined that each member of our audit committee qualifies as an "independent director" for purposes of serving on an audit committee under the Exchange Act and Nasdaq listing requirements. Our board of directors has determined that Avraham Berger qualifies as an "audit committee financial expert," as defined in Item 407(d)(5) of Regulation S-K. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq.

Audit Committee Role

Our audit committee generally provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting and internal control functions by reviewing the services of our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants. Our audit committee also acts as a corporate governance compliance committee and oversees the implementation and amendment, from time to time, of our policies for compliance with Israeli and U.S. securities laws and applicable Nasdaq corporate governance requirements, including non-use of inside information, reporting requirements, our engagement with related parties, whistleblower complaints and protection, and is also responsible for the handling of any incidents that may arise in violation of our policies or applicable securities laws. Our board of directors has adopted an audit committee charter setting forth the specific responsibilities of the audit committee consistent with the Companies Law, and the rules and regulations of the SEC and the Nasdaq listing requirements, which include:

- oversight of our independent auditors and recommending the engagement, compensation or termination of engagement of our independent auditors to the board of directors or shareholders for their approval, as applicable, in accordance with the requirements of the Companies Law;
- pre-approval of audit and non-audit services to be provided by the independent auditors;
- reviewing and recommending to the board of directors approval of our quarterly and annual financial reports; and
- overseeing the implementation and amendment of our policies for compliance with Israeli and U.S. securities laws and applicable Nasdaq corporate governance requirements.

Additionally, under the Companies Law, the role of the audit committee includes: (1) determining whether there are delinquencies in the business management practices of our company, including in consultation with our internal auditor or our independent auditor, and making recommendations to the board of directors to improve such practices; (2) determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest) and whether any such transaction is an extraordinary or material transaction under the Companies Law; (3) determining whether a competitive process must be implemented for the approval of certain transactions with controlling shareholders or in which a controlling shareholder has a personal interest (whether or not the transaction is an extraordinary transaction), under the supervision of the audit committee or other party determined by the audit committee and in accordance with standards determined by the audit committee, or whether a different process determined by the audit committee should be implemented for the approval of such transactions; (4) determining the process for the approval of certain transactions with controlling shareholders that the audit committee has determined are not extraordinary transactions but are not immaterial transactions; (5) where the board of directors approves the work plan of the internal auditor, examining such work plan before its submission to the board of directors and proposing amendments thereto; (6) examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities; (7) examining the scope of our auditor's work and compensation and submitting its recommendation with respect thereto to the corporate body considering the appointment thereof (either the board of directors or the shareholders at the general meeting); and (8) establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Compensation Committee

We have a compensation committee consisting of Mr. Leon Recanati, Mr. Avraham Berger, Ms. Karnit Goldwasser and Ms. Lilach Asher-Topilsky. Mr. Recanati serves as the chairman of the compensation committee.

In accordance with regulations promulgated under the Companies Law described above, we elected to "opt out" from the Companies Law requirement to appoint external directors and related rules concerning the composition of the audit committee and compensation committee. Under such exemption, among other things, the composition of our compensation committee must comply with the requirements of Nasdaq rules. Under Nasdaq listing requirements, we are required to maintain a compensation committee consisting of at least two members, each of whom is an "independent director" under the Nasdaq listing requirements. Our board of directors has affirmatively determined that each member of our compensation committee qualifies as an "independent director" under the Nasdaq listing requirements.

Compensation Committee Role

In accordance with the Companies Law, the roles of the compensation committee are, among others, as follows:

- recommending to the board of directors with respect to the approval of the compensation policy for office holders and, once every three years, regarding any extensions to a compensation policy that was adopted for a period of more than three years;
- reviewing the implementation of the compensation policy and periodically recommending to the board of directors with respect to any amendments or updates of the compensation policy;
- resolving whether or not to approve arrangements with respect to the terms of office and employment of office holders; and
- exempting, under certain circumstances, a transaction with our Chief Executive Officer from the approval of the general meeting of our shareholders.

We rely on the "foreign private issuer exemption" with respect to the Nasdaq requirement to have a formal charter for the compensation committee.

Strategy Committee

Our strategy committee currently consists of Mr. Jonathan Hahn, Ms. Lilach Asher-Topilsky, Mr. Amiram Boehm and Mr. David Tsur. Mr. Jonathan Hahn serves as the chairman of the strategy committee.

The roles of our strategy committee are (among others): (1) reviewing periodically and making recommendations to the board of directors with respect to our strategic plan and overall strategy, our research and development plan, annual work plan and budget, strategy with respect to mergers and acquisitions, and any strategic initiatives identified our board of directors or management from time to time, including the exit from existing lines of business and entry into newlines of business, joint ventures, acquisitions, investments, dispositions of business and assets and business expansions; (2) guiding management in the development of our strategy, including reviewing and discussing with management our strategic direction and initiatives and the risks and opportunities associated with our strategy; (3) reviewing with management the process for development, approval and modification of the strategy and strategic plan; (4) assisting management with identifying key issues, options and external developments impacting our strategy; (5) reviewing management's progress in implementing our global strategy; and (6) ensuring the board of directors is regularly apprised of the progress with respect to implementation of any approved strategy.

Internal Auditor

Under the Companies Law, the board of directors of a public company must appoint an internal auditor recommended by the audit committee. The role of the internal auditor is, among other things, to examine whether a company's actions comply with applicable law and orderly business procedure. Under the Companies Law, the internal auditor may not be an "interested party" or an office holder, or a relative of an interested party or of an office holder, nor may the internal auditor be the company's independent accounting firm or anyone acting on its behalf. An "interested party" is defined in the Companies Law as (i) a holder of 5% or more of the company's outstanding shares or voting rights, (ii) any person or entity (or relative of such person) who has the right to designate one or more directors or to designate the chief executive officer of the company, or (iii) any person who serves as a director or as a chief executive officer of the company. Linur Dloomy of Brightman Almagor Zohar & Co. (a Firm in the Deloitte Global Network) serves as our internal auditor.

Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law

Fiduciary Duties of Office Holders

The Companies Law codifies the fiduciary duties that office holders owe to a company. Each person listed in the table under "Management — Executive Officers and Directors" is an office holder under the Companies Law.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes, among other things, a duty to use reasonable means, in light of the circumstances, to obtain:

- information on the advisability of a given action brought for his or her approval or performed by the director in his or her capacity as a director; and

- all other important information pertaining to such action.

The duty of loyalty requires an office holder to act in good faith and for the benefit of the company, and includes, among other things, the duty to:

- refrain from any act involving a conflict of interests between the performance of his or her duties to the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the business of the company;
- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

We may approve an act specified above which would otherwise constitute a breach of the office holder's duty of loyalty provided that the office holder acted in good faith, the act or its approval does not harm the company and the office holder discloses his or her personal interest a sufficient amount of time before the date for discussion of approval of such act.

Disclosure of Personal Interests of an Office Holder and Approval of Transactions

The Companies Law requires that an office holder promptly disclose to the company any "personal interest" that he or she may have, and all related material information or documents relating to any existing or proposed transaction by the company. A "personal interest" is defined under the Companies Law as the personal interest of a person in an action or in a transaction of the company, including the personal interest of such person's relative or of any other corporate entity in which such person and/or such person's relative is a director, general manager or chief executive officer, a holder of 5% or more of the outstanding shares or voting rights, or has the right to appoint at least one director or the general manager, but excluding a personal interest arising solely from ownership of shares in the company. A personal interest includes the personal interest of a person for whom the office holder holds a voting proxy and the personal interest of a person voting as a proxy, even when the person granting such proxy has no personal interest. An interested office holder's disclosure must be made promptly and no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obliged to disclose such information if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered as an "extraordinary transaction."

An "extraordinary transaction" is defined under the Companies Law as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that is likely to have a material impact on the company's profitability, assets or liabilities.

Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder or with a third party in which the office holder has a personal interest, and which is not an extraordinary transaction, requires approval by the board of directors. Our articles of association do not provide for a different method of approval. If the transaction is an extraordinary transaction with an office holder or third party in which the office holder has a personal interest, then audit committee approval is required prior to approval by the board of directors. The audit committee determines whether any such transaction is an "extraordinary transaction" (within the meaning of the Companies Law). For the approval of compensation arrangements with directors and officers who are controlling shareholders, see "— Disclosures of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions," for the approval of compensation arrangements with directors, see "— Compensation of Directors" and for the approval of compensation arrangements with office holders who are not directors, see "— Compensation of Executive Officers."

Subject to certain exceptions, any person who has a personal interest in the approval of a transaction that is brought before a meeting of the board of directors or the audit committee may not be present at the meeting, unless such person is an office holder and invited by the chairman of the board of directors or of the audit committee, as applicable, to present the matter being considered, and may not vote on the matter. In addition, a director who has a personal interest in the approval of a transaction may be present at the meeting and vote on the matter if a majority of the directors or members of the audit committee, as applicable, have a personal interest in the transaction. In such case, shareholder approval is also required.

Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions

Pursuant to the Companies Law, the disclosure requirements regarding personal interests that apply to office holders also apply to a controlling shareholder of a public company. For this purpose, a controlling shareholder is a shareholder who has the ability to direct the activities of a company, including a shareholder who owns 25% or more of the voting rights if no other shareholder owns more than 50% of the voting rights. Two or more shareholders with a personal interest in the approval of the same transaction are deemed to be one shareholder.

Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, the terms of services provided by a controlling shareholder or his or her relative, directly or indirectly (including through a corporation controlled by a controlling shareholder), the terms of employment of a controlling shareholder or his or her relative who is employed by the company and who is not an office holder and the terms of service and employment, including exculpation, indemnification or insurance, of a controlling shareholder or his or her relative who is an office holder, require the approval of each of the audit committee or the compensation committee with respect to terms of service and employment by the company as an office holder, employee or service provider, the board of directors and the shareholders, in that order. In addition, the shareholder approval must fulfill one of the following requirements:

- at least a majority of the shares held by shareholders who have no personal interest in the transaction and who are present and voting at the meeting on the matter are voted in favor of approving the transaction, excluding abstentions; or

- the shares voted against the transaction by shareholders who have no personal interest in the transaction who are present and voting at the meeting represent no more than 2% of the voting rights in the company.

Each shareholder voting on the approval of an extraordinary transaction with a controlling shareholder must inform the company prior to voting whether or not he or she has a personal interest in the approval of the transaction, otherwise, the shareholder is not eligible to vote on the proposal and his or her vote will not be counted for purposes of the proposal.

Any extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest with a term of more than three years requires approval every three years, unless the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors, relating to terms of service or employment, that would otherwise require approval of the shareholders may be exempt from shareholder approval upon certain determinations of the audit committee and board of directors.

Duties of Shareholders

Under the Companies Law, a shareholder has a duty to refrain from abusing his or her power in the company and to act in good faith and in a customary manner in exercising its rights and performing its obligations to the company and other shareholders, including, among other things, when voting at meetings of shareholders on the following matters:

- an amendment to the company's articles of association;

- an increase in the company's authorized share capital;

- a merger; and

- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

In addition, certain shareholders have a duty to act with fairness towards the company. These shareholders include any controlling shareholder, any shareholder who knows that his or her vote can determine the outcome of a shareholder vote, and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder or has another power with respect to the company. The Companies Law does not define the substance of this duty except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness.

Approval of Significant Private Placements

Under the Companies Law, a significant private placement of securities requires approval by the board of directors and the shareholders by a simple majority. A private placement is considered a significant private placement if it will cause a person to become a controlling shareholder or if all of the following conditions are met:

- the securities issued amount to 20% or more of the company's outstanding voting rights before the issuance;

- some or all of the consideration is other than cash or listed securities or the transaction is not on market terms; and

- the transaction will increase the relative holdings of a shareholder who holds 5% or more of the company's outstanding share capital or voting rights or that will cause any person to become, as a result of the issuance, a holder of more than 5% of the company's outstanding share capital or voting rights.

Compensation of Directors and Executive Officers

Aggregate Compensation of Directors and Officers

The aggregate compensation incurred by us in relation to our executive officers and directors, including share-based compensation, for the year ended December 31, 2020, was approximately $4.2 million. This amount includes approximately $0.3 million set aside or accrued to provide pension, severance, retirement or similar benefits or expenses, but does not include business travel, professional and business association dues and expenses reimbursed to executive officers, and other benefits commonly reimbursed or paid by companies in Israel.

From time to time, we grant options and, in the past, granted restricted share units to our officers and directors. During the year ended December 31, 2020, we granted to our directors and chief executive officer options to purchase an aggregate of 222,000 ordinary shares and 90,000 ordinary shares, respectively, at a weighted average exercise price of NIS 23.93 per share and NIS 21.34 per share, respectively, under our 2011 Israeli Share Award Plan. In addition, in 2020 we granted to our chief executive officer 30,000 restricted share units, under our 2011 Israeli Share Award Plan. As of December 31, 2020, options to purchase 848,334 of our ordinary shares granted to our officers and directors as a group were outstanding, of which options to purchase 328,896 of our ordinary shares were vested, with a weighted average exercise price of NIS 18.94 per ordinary share. As of December 31, 2020, 79,146 restricted share units granted to our officers as a group were outstanding. For details regarding the beneficial ownership of our shares by our officers and directors, see "Item 6. Directors, Senior Management and Employees — Share Ownership."

Compensation of Directors

We pay our directors an annual fee and per-meeting fees in the maximum amounts payable from time to time for such fees by us under the Second and Third Addendums, respectively (or, to the extent any director is determined to have financial and accounting expertise and is deemed an expert director (in each case, within the meaning of the Companies Law and the regulations thereunder), under the Fourth Addendum) to the Israeli Companies Regulations (Rules Regarding Compensation and Expense Reimbursement of External Directors), 2000, or the Compensation Regulations. In accordance with the Compensation Regulations, we currently pay our directors an annual fee of NIS 86,403 (approximately $25,151), as well as a fee of NIS 3,296 (approximately $963) for each board or committee meeting attended in person, NIS 1978 (approximately 578) for each board or committee meeting attended via telephone or videoconference and NIS 1,658 (approximately $485) for participation by written consent.

There are no arrangements or understandings between us, on the one hand, and any of our directors, on the other hand, providing for benefits upon termination of their service as directors of our company.

To our knowledge, there are no agreements and arrangements between any director and any third party relating to compensation or other payment in connection with their candidacy or service on our Board of Directors.

Compensation of Covered Executives

The following table presents information regarding compensation accrued in our financial statements for our five most highly compensated office holders (within the meaning of the Companies Law), namely our Chief Executive Officer, Vice President, Clinical Development and Medical Director, Chief Financial Officer, Vice President, Operations and Vice President, Research and Development and IP, during or with respect to the year ended December 31, 2020. Each such office holder was covered by our directors' and officers' liability insurance policy and was entitled to indemnification and exculpation in accordance with indemnification and exculpation agreements, our articles of association and applicable law.

Name and Position	Salary[1]	Bonus[2]	Value of Options Granted[3]	Other[4]	Total
			(in thousands)		
Amir London *Chief Executive Officer*	$ 406	$ 194	$ 212	$ 28	$ 840
Naveh Tov *Vice President, Clinical Development and Medical Director*	$ 256	$ 62	$ 28	$ 17	$ 363
Chaime Orlev *Chief Financial Officer*	$ 254	$ 62	$ 30	$ 16	$ 362
Eran Nir *Vice President, Operations*	$ 239	$ 61	$ 31	$ 28	$ 359
Michal Ayalon, PhD *Vice President, Research and Development and IP*	$ 213	$ 55	$ 31	$ 15	$ 314

(1) Salary includes gross salary and fringe benefits.

(2) Bonuses includes annual bonuses. The annual bonus is subject to the fulfillment of certain targets determined for each year by the compensation committee and board of directors.

(3) The value of options is the expense recorded in our financial statements for the period ended December 31, 2020 with respect to all options granted to such executive officer.

(4) Cost of use of company car.

Agreements with Five Most Highly Compensated Office Holders

We have entered into agreements with each of our five most highly compensated office holders (within the meaning of the Companies Law), listed below. The terms of employment or service of such office holders are directed by our compensation policy. See below "— Compensation Policy." Each of these agreements contains provisions regarding non-competition, confidentiality of information and assignment of inventions. The non-competition provision applies for a period that is generally 12 months following termination of employment. The enforceability of covenants not to compete in Israel and the United States is subject to limitations. Such office holders are entitled to an annual bonus subject to the fulfillment of certain targets determined for each year by the compensation committee and board of directors. In addition, all such executive officers are entitled to a company car, as well as sick pay, convalescence pay, manager's insurance and a study fund ("*keren hishtalmut*") and annual leave, all in accordance with Israeli law and our compensation policy for executive officers.

Amir London, Chief Executive Officer. Mr. London has served as our Chief Executive Officer since July 2015. Prior to that and effective as of December 1, 2013, Mr. London served as our Vice President, Business Development. Mr. London's engagement terms as our Chief Executive Officer have been approved by our Compensation Committee, Board of Directors and shareholders. According to the terms of the agreement, either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Dr. Naveh Tov, Vice President, Clinical Development and Medical Director. Effective as of July 2016, we entered into an employment agreement with Dr. Naveh Tov with respect to his employment as our Vice President, Clinical Development and Medical Director. Either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law. Pursuant to an amendment to his employment agreement, effective as of April 1, 2021, Dr. Tov will cease to serve in such position and will serve as Medical Advisor in a 20% part time position.

Chaime Orlev, Chief Financial Officer. Effective as of October 1, 2017, we entered into an employment agreement with Mr. Chaime Orlev with respect to his employment as our Chief Financial Officer. Either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Eran Nir, Vice President, Operations. Effective as of November 1, 2016, we entered into an employment agreement with Mr. Eran Nir with respect to his employment as our Vice President, Operations. Either party may terminate the agreement at any time upon two months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Michal Ayalon, PhD*, Vice President, Research and Development and IP.* Effective as of February 1, 2019, we entered into an employment agreement with Ms. Michal Ayalon, PhD with respect to her employment as our Vice President, *Research and Development and IP*. Either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Other Executive Officers

We have entered into written employment agreements with the rest of our executive officers. The terms of employment of our executive office holders are directed by our compensation policy. See "— Compensation Policy." Each of these agreements contains provisions regarding non-competition, confidentiality of information and assignment of inventions. The non-competition provision applies for a period that is generally 12 months following termination of employment. The enforceability of covenants not to compete in Israel and the United States is subject to limitations. In addition, we are required to provide up to three months' notice prior to terminating the employment of such executive officers, other than in the case of a termination for cause. Each of our employment agreements with such executive officers provides for annual bonuses, which are subject to the fulfillment of certain targets determined for each year, and the executive officers are also entitled to special bonuses upon the achievement of certain company milestones.

Compensation of Directors and Executive Officers

Compensation Policy.

Under the Companies Law, a public company is required to adopt a compensation policy, which sets forth the terms of service and employment of office holders, including the grant of any benefit, payment or undertaking to provide payment, any exemption from liability, insurance or indemnification, and any severance payment or benefit. Such compensation policy must comply with the requirements of the Companies Law. The compensation policy must be approved at least once every three years, first, by our board of directors, upon recommendation of our compensation committee, and second, by the shareholders by a special majority. Our current compensation policy for executive officers and compensation policy for directors were each approved by our shareholders on March 25, 2020 and were amended by our shareholders on December 10, 2020.

Compensation of Directors

Under the Companies Law, the compensation (including insurance, indemnification, exculpation and compensation) of our directors requires the approval of our compensation committee, the subsequent approval of the board of directors and, unless exempted under the regulations promulgated under the Companies Law, the approval of the shareholders at a general meeting. The approval of the compensation committee and board of directors must be in accordance with the compensation policy. In special circumstances, the compensation committee and board of directors may approve a compensation arrangement that is inconsistent with the company's compensation policy, provided that they have considered the same considerations and matters required for the approval of a compensation policy in accordance with the Companies Law, in which case the approval of the company's shareholders must be by a special majority (referred to as the "Special Majority for Compensation") that requires that either:

- a majority of the shares held by shareholders who are not controlling shareholders and shareholders who do not have a personal interest in such matter and who are present and voting at the meeting, are voted in favor of approving the compensation package, excluding abstentions; or

- the total number of shares voted by non-controlling shareholders and shareholders who do not have a personal interest in such matter that are voted against the compensation package does not exceed 2% of the aggregate voting rights in the company.

Where the director is also a controlling shareholder, the requirements for approval of transactions with controlling shareholders apply, as described above under "— Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions."

Compensation of Officers Other than the Chief Executive Officer

Pursuant to the Companies Law, the compensation (including insurance, indemnification and exculpation) of a public company's office holders (other than directors, which is described above, and the chief executive officer, which is described below) generally requires approval first by the compensation committee and second by the company's board of directors, according to the company's compensation policy. In special circumstances the compensation committee and board of directors may approve a compensation arrangement that is inconsistent with the company's compensation policy, provided that they have considered the same considerations and matters required for the approval of a compensation policy in accordance with the Companies Law and such arrangement must be approved by the company's shareholders by the Special Majority for Compensation. However, if the shareholders of the company do not approve a compensation arrangement with an executive officer that is inconsistent with the company's compensation policy, the compensation committee and board of directors may, in special circumstances, override the shareholders' decision, subject to certain conditions.

Under the Companies Law, an amendment to an existing arrangement with an office holder (other than the chief executive officer, which is described below) who is not a director requires only the approval of the compensation committee, if the compensation committee determines that the amendment is not material in comparison to the existing arrangement. However, according to regulations promulgated under the Companies Law, an amendment to an existing arrangement with an office holder (who is not a director) who is subordinate to the chief executive officer shall not require the approval of the compensation committee, if (i) the amendment is approved by the chief executive officer and the company's compensation policy determines that a non-material amendment to the terms of service of an office holder (other than the chief executive officer) will be approved by the chief executive officer and (ii) the engagement terms are consistent with the company's compensation policy. Under our compensation policy for executive officers and subject to applicable law, our chief executive officer may approve an immaterial amendment of up to 10% of the existing terms of office and engagement (as compared to those approved by the compensation committee) of an executive who is subordinate to the chief executive officer (who is not a director).

Compensation of Chief Executive Officer

The compensation (including insurance, indemnification and exculpation) of a public company's chief executive officer generally requires the approval of first, the company's compensation committee; second, the company's board of directors; and third (except for limited exceptions), the company's shareholders by the Special Majority for Compensation. If the shareholders of the company do not approve the compensation arrangement with the chief executive officer, the compensation committee and board of directors may override the shareholders' decision, subject to certain conditions. The compensation committee and board of directors approval should be in accordance with the company's compensation policy; however, in special circumstances, they may approve compensation terms of a chief executive officer that are inconsistent with such policy provided that they have considered the same considerations and matters required for the approval of a compensation policy in accordance with the Companies Law and that shareholder approval was obtained by the Special Majority for Compensation. Under certain circumstances, the compensation committee and board of directors may waive the shareholder approval requirement in respect of the compensation arrangements with a candidate for chief executive officer if they determine that the compensation arrangements are consistent with the company's stated compensation policy.

However, an amendment to an existing arrangement with an executive officer (who is not a director) requires only the approval of the compensation committee, if the compensation committee determines that the amendment is not material in comparison to the existing arrangement. Furthermore, according to regulations promulgated under the Companies Law, the renewal or extension of an existing arrangement with a chief executive officer shall not require shareholder approval if (i) the renewal or extension is not beneficial to the chief executive officer as compared to the prior arrangement or there is no substantial change in the terms and other relevant circumstances; and (ii) the engagement terms are consistent with the company's compensation policy and the prior arrangement was approved by the shareholders by the Special Majority for Compensation.

Where the office holder is also a controlling shareholder, the requirements for approval of transactions with controlling shareholders apply, as described above under "— Disclosure of Personal Interests of a Controlling Shareholders and Approval of Certain Transactions."

Exculpation, Insurance and Indemnification of Office Holders

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care, but only if a provision authorizing such exculpation is included in the company's articles of association. Our articles of association include such a provision. However, we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law). We may also not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Companies Law, a company may indemnify an office holder for the following liabilities, payments and expenses incurred for acts performed by him or her, as an office holder, either pursuant to an undertaking given by the company in advance of the act or following the act, provided its articles of association authorize such indemnification:

- a monetary liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount, or according to criteria, determined by the board of directors as reasonable under the circumstances. Such undertaking shall detail the foreseen events and amount or criteria mentioned above;

- reasonable litigation expenses, including reasonable attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent (*mens rea*); and (2) in connection with a monetary sanction; and

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent (*mens rea)*.

In addition, under the Companies Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder, to the extent provided in the company's articles of association:

- a breach of a duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;

- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder; and

- a monetary liability imposed on the office holder in favor of a third party.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;

- a breach of the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;

- an act or omission committed with intent to derive illegal personal benefit; or

- a fine or penalty levied against the office holder.

For the approval of exculpation, indemnification and insurance of office holders who are directors, see "— Compensation of Directors," for the approval of exculpation, indemnification and insurance of office holders who are not directors, see "—Compensation of Executive Officers" and for the approval of exculpation, indemnification and insurance of office holders who are controlling shareholders, see "— Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law — Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions."

Our articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted under the Companies Law (other than indemnification for litigation expenses in connection with a monetary sanction); provided that we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law).

We have entered into indemnification and exculpation agreements with each of our current office holders exculpating them from a breach of their duty of care to us to the fullest extent permitted by the Companies Law (provided that we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law)) and undertaking to indemnify them to the fullest extent permitted by the Companies Law (other than indemnification for litigation expenses in connection with a monetary sanction), to the extent that these liabilities are not covered by insurance. This indemnification is limited to events determined as foreseeable by our board of directors based on our activities, as set forth in the indemnification agreements. Under such agreements, the maximum aggregate amount of indemnification that we may pay to all of our office holders together is (i) for office holders who joined our company before May 31, 2013, the greater of 30% of the shareholders equity according to our most recent financial statements (audited or reviewed) at the time of payment and NIS 20 million, and (ii) for office holders who joined our company after May 31, 2013, 25% of the shareholders equity according to our most recent financial statements (audited or reviewed) at the time of payment.

We are not aware of any pending or threatened litigation or proceeding involving any of our office holders as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any office holder.

Employees

As of December 31, 2020, we employed 408 employees, all of whom in Israel, according to the following division: 211 in Operations, 102 in Quality, 16 in Research and Development, 17 in Regulation, 2 in Business Development, 8 in Medical & Clinical, 13 in sales, Israel, 15 in Human Resources & Administration, 21 in Finance and 2 in Legal. As of December 31, 2019, we employed 429 employees, according to the following division: 224 in Operations, 108 in Quality, 20 in Research and Development, 17 in Regulation, 4 in Business Development, 10 in Medical & Clinical, 9 in sales, Israel, 15 in Human Resources & Administration and 22 in Finance. As of December 31, 2018, we employed 408 employees, according to the following division: 202 in Operations, 104 in Quality, 20 in Research and Development, 17 in Regulation, 19 in Business Development, 8 in Medical & Clinical, 14 in Human Resources& Administration and 24 in Finance.

We signed a collective bargaining agreement with the Histadrut (General Federation of Labor in Israel) and the employees' committee established by our employees at our Beit Kama facility in December 2013, which expired in December 2017. The collective bargaining agreement governs certain aspects of our employee-employer relations, such as: firing procedures, annual salary raise, eligibility for certain compensation terms and welfare. In July 2018, during the course of our negotiations with the Histadrut and the employees' committee on the extension of the collective bargaining agreement beyond the December 2017 expiration, the employee's committee commenced a labor strike, which continued for approximately one month. In November 2018, we signed a new collective bargaining agreement with the employees' committee and the Histadrut, which will expire in December 2021. Approximately 60% of our employees, all of whom are located at our Beit Kama facility, currently work under the collective bargaining agreement signed in November 2018. In December 2020, during the course of our negotiations with the Histadrut and the employees' committee on severance remuneration for employees who may be laid-off as part of the workforce down-sizing planned for 2021 as a result of the transfer of GLASSIA manufacturing to Takeda, the employee's committee declared a labor dispute, which was subsequently concluded during February 2021 following the execution of a special collective bargaining agreement governing such severance terms.

Israeli labor laws govern the length of the workday, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination of employment, equal opportunity and anti-discrimination laws and other conditions of employment. Subject to certain exceptions, Israeli law generally requires severance pay upon the retirement, death or dismissal of an employee, and requires us and our employees to make payments to the National Insurance Institute, which is similar to the U.S. Social Security Administration. Our employees have defined benefit pension plans that comply with the applicable Israeli legal requirements.

Extension orders issued by the Ministry of Labor, Social Affairs, and Social Services apply to us and affect matters such as cost of living adjustments to payroll, length of working hours and week, recuperation pay, travel expenses, and pension rights.

Share Ownership

The following table sets forth information with respect to the beneficial ownership of our ordinary shares by each of our directors and executive officers and all of current directors and executive officers as a group.

The percentage of beneficial ownership of our ordinary shares is based on 44,745,364 ordinary shares outstanding as of February 24, 2020 Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting power or investment power with respect to securities. All ordinary shares subject to options exercisable into ordinary shares and restricted share units that will become vested, as applicable, within 60 days of the date of the table are deemed to be outstanding and beneficially owned by the shareholder holding such options and restricted share units for the purpose of computing the number of shares beneficially owned by such shareholder. They are not, however, deemed to be outstanding and beneficially owned for the purpose of computing the percentage ownership of any other shareholder.

Name	Ordinary Shares Beneficially Owned	
	Number	Percentage
Executive Officers		
Amir London (1)	138,750	*
Chaime Orlev (2)	37,194	*
Michal Ayalon (3)	20,119	
Yael Brenner (4)	12,699	*
Hanni Neheman (5)	23,956	*
Eran Nir (6)	33,345	*
Yifat Philip	-	-
Orit Pinchuk (7)	49,531	*
Ariella Raban (8)	41,117	*
Dr. Naveh Tov (9)	55,860	*
Directors		
Lilach Asher Topilsky(10)	6,625	*
Avraham Berger (11)	23,188	*
Amiram Boehm(12)	6,625	*
Ishay Davidi (13)	9,459,333	21.1%
Karnit Goldwasser(14)	6,625	*
Jonathan Hahn (15)	1,931,706	4.3%
Leon Recanati (16)	3,606,311	8.0%
Ari Shamiss	-	-
David Tsur (17)	708,369	1.6%
Directors and executive officers as a group (19 persons)(18)	16,161,353	36.0%

* Less than 1% of our ordinary shares.

(1) Includes (i) 15,375 ordinary shares (ii) 23,250 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 100,125 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.25 (or $5.99) per share, which expire between March 2, 2023 and September 25, 2026. Does not include unvested options to purchase 115,875 ordinary shares and 38,625 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(2) Includes (i) 6,853 ordinary shares, (ii) 7,585 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 22,756 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 18.95 (or $5.90) per share, which expire between May 12, 2024 and December 20, 2025. Does not include unvested options to purchase 12,144 ordinary shares and 4,047 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(3) Includes (i)3,586 ordinary shares, (ii) 4,133 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 12,400 ordinary shares exercisable within 60 days of the date of the table, at exercise price of NIS 20.55(or $6.39) per share, which expire between August 1, 2025 and December 20, 2025. Does not include unvested options to purchase 13,800 ordinary shares and 4,600 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(4) Includes (i) 2,032 ordinary shares, (ii) 2,667 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 8,000 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 20.79 (or $6.47) per share, which expire between January 31, 2024 and December 20, 2025. Does not include unvested options to purchase 10,800 ordinary shares and 3,600 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(5) Includes (i) 2,019 ordinary shares, (ii) 2,234 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 19,703 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 18.02 (or $5.61) per share, which expire between October 27, 2021 and December 20, 2025. Does not include unvested options to purchase 3,547 ordinary shares and 1,182 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(6) Includes (i) 6,163 ordinary shares, (ii) 6,798 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 20,384 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 20.68 (or $6.43) per share, which expire between May 24, 2023 and December 20, 2025. Does not include unvested options to purchase 10,800 ordinary shares and 3,600 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(7) Includes (i) 7,898 ordinary shares, (ii) 8,533 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 33,100 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 19.21 (or $5.98) per share, which expire between October 27, 2021 and December 20, 2025. Does not include unvested options to purchase 10,800 ordinary shares and 3,600 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(8) Includes (i) 5,334 ordinary shares, (ii) 5,946 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 29,838 ordinary shares exercisable within 60 days of the date of the table, at an exercise price of NIS 18.76 (or $5.84) per share, which expire between October 27, 2021 and December 20, 2025. Does not include unvested options to purchase 11,363 ordinary shares and 3,787 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(9) Includes (i) 10,060 ordinary shares, (ii) 10,700 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 35,100 ordinary shares exercisable within 60 days of the date of the table, at an exercise price of NIS 18.53 (or $5.76) per share, which expire between October 27, 2021 and December 20, 2025. Does not include unvested options to purchase 10,800 ordinary shares and 3,600 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(10) Subject to options to purchase 6,625 ordinary shares that are currently exercisable or exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 23.67 (or $7.36) per share, which expire on September 25, 2026. Does not include unvested options to purchase 19,875 ordinary shares that are not exercisable within 60 days of the date of the table.

(11) Subject to options to purchase 23,188 ordinary shares that are currently exercisable or exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 20.79 (or $6.47) per share, which expire between March 2, 2023 and September 25, 2026. Does not include unvested options to purchase 28,313 ordinary shares that are not exercisable within 60 days of the date of the table.

(12) Subject to options to purchase 6,625 ordinary shares that are currently exercisable or exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 23.67 (or $7.36) per share, which expire on September 25, 2026. Does not include unvested options to purchase 19,875 ordinary shares that are not exercisable within 60 days of the date of the table.

(13) Includes (i) 9,452,708 shares indirectly beneficially owned through FIMI Opportunity Fund 6, L.P. and FIMI Israel Opportunity Fund 6, Limited Partnership. See footnote (1) "Item 7. Major Shareholders and Related Party Transactions—Major Shareholders"; and (ii) 6,625 ordinary shares subject to options held directly held by Mr. Ishay Davidi that are currently exercisable or exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 23.67 (or $7.36) per share, which expire on September 25, 2026. Does not include unvested options to purchase 19,875 ordinary shares held by Mr. Ishay Davidi that are not exercisable within 60 days of the date of the table.

(14) Subject to options to purchase 6,625 ordinary shares that are currently exercisable or exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 23.67 (or $7.36) per share, which expire on September 25, 2026. Does not include unvested options to purchase 19,875 ordinary shares that are not exercisable within 60 days of the date of the table.

(15) Mr. Hahn holds 25% of the shares of Sinara, which holds 100% of the shares of Damar, which directly holds 1,903,518 ordinary shares. Also includes options to purchase 28,188 ordinary shares directly held by Mr. Jonathan Hahn that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 20.43 (or $6.35) per share, which expire between October 27, 2021 and September 25, 2026. Does not include unvested options to purchase 28,313 ordinary shares held by Mr. Jonathan Hahn that are not exercisable within 60 days of the date of the table

(16) Mr. Recanati holds 677,479 ordinary shares directly and 2,895,644 ordinary shares indirectly through Gov Financial Holdings Ltd., a company organized under the laws of the State of Israel ("**Gov**"). Gov is wholly-owned by Mr. Recanati, the Chairman of our Board of Directors, who exercises sole voting and investment power over the shares held by Gov. In addition, includes options to purchase 33,188 ordinary shares directly held by Mr. Recanati that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.64 (or $6.11) per share, which expire between October 27, 2021 and September 25, 2026. Does not include unvested options to purchase 28,813 ordinary shares that are not exercisable within 60 days of the date of the table.

(17) Mr. David Tsur directly holds 680,181 ordinary shares. In addition, includes options to purchase 28,188 ordinary shares directly held by Mr. Tsur that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.80 (or $6.16) per share, which expire between March 02, 2023 and September 25, 2026. Does not include unvested options to purchase 28,313 ordinary shares that are not exercisable within 60 days of the date of the table.

(18) See footnotes (1)-(17) for certain information regarding beneficial ownership.

Equity Compensation Plans

In 2005, we adopted our 2005 Israeli Share Option Plan (the "2005 Plan"). We ceased to grant options under the 2005 Plan in 2010 and the 2005 Plan expired on July 5, 2015.

In July 2011, we adopted our 2011 Israeli Share Option Plan and in September 2016, we amended and renamed it as the 2011 Israeli Share Award Plan (the "2011 Plan"). Under the 2011 Plan, we are authorized to grant options and restricted share units to directors, officers, employees, consultants and service providers of our company and subsidiaries. The 2011 Plan is intended to enhance our ability to attract and retain desirable individuals by increasing their ownership interests in us. The 2011 Plan, which is effective until July 23, 2021, is designed to reflect the provisions of the Israeli Tax Ordinance, which affords certain tax advantages to Israeli employees, officers and directors that are granted options in accordance with its terms. The 2011 Plan may be administered by our board of directors either directly or upon the recommendation of the compensation committee.

We have granted options to our employees, officers and directors under the 2011 Plan. Each option granted under the 2011 Plan entitles the grantee to purchase one of our ordinary shares. In general, the exercise price of options granted to directors and officers under the 2011 Plan prior to January 1, 2020, is generally equal to the higher of (i) the average closing price of our ordinary shares on the TASE during the 30-TASE trading days immediately prior to board approval of the grant of such options plus 5%; and (ii) the closing price of our ordinary shares on the TASE on the date of the approval of the grant of options. The exercise price of options granted to directors and officers under the 2011 Plan following January 1, 2020 is generally equal to the higher of (i) the average closing price of our ordinary shares on the TASE during the 30-TASE trading days immediately prior to board approval of the grant of such options; and (ii) the closing price of our ordinary shares on the TASE on the date of the approval of the grant of options. Options granted under the 2011 Plan are exercised by way of net exercise and accordingly, the grantee is not required to pay the exercise price when exercising the options and instead, receives, upon exercise and sale of such number of ordinary shares, an amount which is equal to the difference between the total market value of the ordinary shares on the date of exercise and sale underlying the exercised options and the total exercise price for such options. The actual number of shares issued pursuant to the net exercise of the options is equal to the number of shares subject to the option less the number of shares tendered back to the company to pay the exercise price.

The options granted under the 2011 Plan prior to January 1, 2020 generally vest during a four-year period following the date of the grant in 13 installments: 25% of the options vest on the first anniversary of the grant date and 6.25% of the remaining options vest at the end of each quarter thereafter. Options granted under the 2011 Plan following January 1, 2020 generally vest in four equal installments, 25% each on each of the four anniversaries of the date of grant. Options granted under the 2011 Plan are generally exercisable for 6.5 years following the date of grant and all unexercised options will expire immediately thereafter. Options that have vested prior to the end of a grantee's employment or services agreement with us may generally be exercised within 90 days from the end of such grantee's employment or services with us, unless such relationship was terminated for cause. Options which are not exercised during such 90-day period expire at the end of the period, unless all of the 90-day period is a black-out period during which time the options may not be exercised, in which case our Chief Executive Officer or Chief Financial Officer is entitled to extend the exercise period for specified periods. Options that have not vested on the date of the end of a grantee's employment or services agreement with us, and, in the event of termination of employment or services for cause, all unexercised options (whether vested or not), expire immediately upon termination.

We have also granted restricted share units to our officers. The restricted share units awarded under the 2011 Plan generally vest over a period of four years in 13 installments: 25% of the restricted share units vest on the first anniversary of the grant date and 6.25% of the remaining restricted share units vest at the end of each quarter thereafter.

In the event of certain transactions, such as our being acquired, or a merger or reorganization or a sale of all or substantially all of our assets, awards then outstanding under the 2011 Plan shall be assumed or substituted for shares or other securities of the surviving or acquiring entity as were distributed to our shareholders in connection and the transaction, subject to an appropriate adjustment to the exercise price (if applicable). The board or the compensation committee may determine that the terms of certain awards under the 2011 Plan include a provision that their vesting schedules will be accelerated such that they will be exercisable prior to the closing of such a transaction, if the awards are not assumed or substituted by the successor company.

Options and restricted share units granted to our employees and Israeli directors under the 2011 Plan were granted pursuant to the provisions of Section 102 of the Israeli Income Tax Ordinance, under the capital gains alternative. In order to comply with the capital gains alternative, all such options and restricted share units under the 2011 Plan are granted or issued to a trustee and are to be held by the trustee for at least two years from the date of grant. Under the capital gains alternative, we are not allowed an Israeli tax deduction for the grant of the options or issuance of the shares issuable thereunder.

As of December 31, 2020, an aggregate of 1,306,718 ordinary shares were reserved for future issuance under the 2011 Plan (subject to certain adjustments specified in the 2011 Plan), and options to purchase 1,660,958 ordinary shares were outstanding under the 2011 Plan, of which options to purchase 799,640 ordinary shares were vested as of such date, and 104,519 restricted share units were outstanding under the 2011 Plan. Any ordinary shares underlying options that expire prior to exercise or restricted share units that are forfeited under the 2011 Plan will become again available for issuance under the 2011 Plan.

Item 7. Major Shareholders and Related Party Transactions

Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares by each person known to us to own beneficially more than 5% of our ordinary shares.

The percentage of beneficial ownership of our ordinary shares is based on 44,745,338 ordinary shares outstanding as of February 24, 2020. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting power or investment power with respect to securities. All ordinary shares subject to options exercisable into ordinary shares within 60 days of the date of the table are deemed to be outstanding and beneficially owned by the shareholder holding such options for the purpose of computing the number of shares beneficially owned by such shareholder. Such shares are also deemed outstanding for purposes of computing the percentage ownership of the person holding the options. They are not, however, deemed to be outstanding and beneficially owned for the purpose of computing the percentage ownership of any other shareholder.

Except as described in the footnotes below, we believe each shareholder has voting and investment power with respect to the ordinary shares indicated in the table as beneficially owned.

Name	Number	Percentage
FIMI Funds(1)	9,452,708	21.1%
Leon Recanati(2)	3,606,311	8.0%

(1) Based solely upon, and qualified in its entirety with reference to, Amendment No. 2 to Schedule 13D filed with the SEC on May 20, 2020. According to the Statement, (i) includes 4,421,909 shares directly owned by FIMI Opportunity Fund 6, L.P. and 5,030,799 shares directly owned by FIMI Israel Opportunity Fund 6, Limited Partnership (together, the "**FIMI Funds**") and (ii) the ordinary shares held by the FIMI Funds are indirectly beneficially owned by (A) FIMI 6 2016 Ltd. ("**FIMI 6**"), which serves as the managing general partner of the FIMI Funds, (B) Mr. Ishay Davidi, Chief Executive Officer of FIMI 6, and (C) Or Adiv Ltd., a company controlled by Mr. Ishay Davidi, which controls FIMI 6. Information included in this footnote does not include 6,625 ordinary shares subject to options held directly by Mr. Davidi's that are currently exercisable or exercisable within 60 days of the date of the table. See Footnote (13) "Item 6. Directors, Senior Management and Employees — Share Ownership."

(2) Mr. Recanati holds 677,479 ordinary shares directly and 2,895,644 ordinary shares indirectly through Gov Financial Holdings Ltd., a company organized under the laws of the State of Israel ("**Gov**"). Gov is wholly-owned by Mr. Recanati, a director and the former Chairman of our Board of Directors, who exercises sole voting and investment power over the shares held by Gov. In addition, includes options to purchase 33,188 ordinary shares directly held by Mr. Recanati that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.64 (or $6.11) per share, which expire between October 27, 2021 and September 25, 2026. Does not include unvested options to purchase 28,813 ordinary shares that are not exercisable within 60 days of the date of the table.

To our knowledge, based on information provided to us by our transfer agent in the United States, as of February 19, 2021, we had one shareholder of record who was registered with an address in the United States, holding approximately 22.9 % of our outstanding ordinary shares. Such number is not representative of the portion of our shares held in the United States nor is it representative of the number of beneficial holders residing in the United States, since such ordinary shares were held of record by one U.S. nominee company, CEDE & Co.

To our knowledge, the only significant changes in the beneficial ownership percentage held by our major shareholders during the past three years have been the following: From January 1, 2018 to the date of this Annual Report, the Hahn family's beneficial ownership decreased from 10.04% to less than 5% during such period. Mr. Leon Recanati's beneficial ownership percentage decreased by 2.95% from 10.99% to 8.05% during such period. The Phoenix Holdings Group beneficial ownership percentage decreased to less than 5% during such period. The DS Apex group's beneficial ownership percentage decreased to less than 5% during such period. The Brosh Capital Partners group's beneficial ownership percentage increased from less than 5% to 7.68% during such period and decreased to less than 5% during such period. The FIMI Funds beneficial ownership percentage increased from less than 5% to 21.14% during such period. Meitav Dash Investments Ltd.'s beneficial ownership percentage decreased to less than 5% during such period.

None of our shareholders has different voting rights from other shareholders. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Related Party Transactions

Tuteur S.A.C.I.F.I.A.

In August 2011, we entered into a distribution agreement with Tuteur that amended and restated a distribution agreement we entered into in November 2001, under which Tuteur was appointed as the exclusive distributor of GLASSIA in Argentina, Paraguay and Uruguay. Tuteur is a company organized under the laws of Argentina and was formerly controlled by Mr. Ralf Hahn, the former Chairman of our board of directors. Mr. Hahn's son, Mr. Jonathan Hahn, a director, is currently the President and a director of Tuteur. On August 19, 2014, we entered into an amendment to the distribution agreement in order to add KamRho(D) as an additional product to be distributed by Tuteur and expanded the territories to include Bolivia. On January 25, 2017, we entered into a second amendment to the distribution agreement, pursuant to which Uruguay was removed from the original territories. On January 21, 2019, we entered into a third amendment to the distribution agreement in order (among other things) to change the terms of payments by Tuteur, change the terms of shipment, appoint a sub-distributor in Paraguay and to extend a fixed discount for the GLASSIA, per vial, sale price in exchange for obtaining a bank guarantee from Tuteur to cover any future supply of products. Tuteur was obligated under the agreement to commence marketing, sales and distribution of the products within each country covered by the agreement within two months after the grant of regulatory approval in each such country. Under the agreement, Tuteur would cease to have exclusivity if it fails to comply with the minimum purchase requirement in each of the countries, on a country-by-country basis. Pursuant to the agreement, Tuteur was obligated to obtain the relevant regulatory approvals and reimbursement in each of the countries within 18 months of receiving the required registration documents from us. GLASSIA was approved by regulators in Argentina in July 2012. GLASSIA has not yet been submitted and approved by regulators in Paraguay or Bolivia. The parties agreed to separately negotiate the allocation of any costs relating to clinical trials or studies required by relevant regulatory authorities in the applicable territory. We retained ownership of all relevant intellectual property. The distribution agreement, as amended, expired on December 31, 2019, and pending the execution of a new distribution agreement, the parties continued to act in accordance with the expired distribution agreement.

In May 2020, we entered into a new distribution agreement with Tuteur, which supersedes the former agreement in its entirety, pursuant to which Tuteur serves as the exclusive distributor of GLASSIA and KamRho(D) IM and IV in Argentina, Paraguay, Bolivia and Uruguay. Under the new distribution agreement, Tuteur is responsible, at its own expense, for obtaining marketing authorization and/or registration for each of the products in the foregoing territories that is not already approved and registered. If Tuteur fails to register any product in any territory within 12 months after receipt of our approval of all relevant documents, we shall be entitled to terminate the agreement with respect to such product or terminate the exclusivity granted to Tuteur with respect to such product. The agreement includes minimum annual purchase commitments by Tuteur, with respect to sales of any products in territories where registration has been completed, commencing as of the effective date of the agreement, and with respect to sale of any products in the other territories, commencing the first year following the registration of any such product in the applicable territory; and the parties agreed to negotiate in good faith the minimum quantities to be purchased by Tuteur in each following marketing year. If Tuteur fails to purchase and pay for the minimum quantity for any product in any marketing year, we are entitled to (i) terminate the agreement on a product-by-product basis and/or (ii) terminate the exclusivity and/or narrow the scope of the territories, if applicable, on a product-by-product basis. The price per product per territory payable by Tuteur pursuant to the agreement will be the higher of 50% of such product's net price sold by Tuteur in the territory or a minimum supply price as defined in the agreement. In addition, Tuteur has undertaken to issue a guarantee (from a U.S., Israeli or a western Europe bank) for every new order of product, in the value of each order, which must be provided prior to the shipment of the product and extended through the complete payment of the amount due on any such order or shipment; such guarantee may not be required to the extent we are able to obtain adequate credit insurance covering the value of each order through its complete payment. We retain ownership of all relevant intellectual property in the products. The agreement is in effect for a period of five years, and thereafter shall automatically renew for additional periods of one year each, unless either party notifies the other party of its desire to terminate the agreement by prior written notice of at least 12 months before the expiration of any of the additional periods. We are entitled to terminate the agreement with respect to all or certain territories in the event of a change of control of Tuteur, its failure to register the products and obtain all marketing approvals within the period set forth above, its failure to purchase and pay for the minimum quantities for two consecutive years (provided that Tuteur will be obligated, during the second marketing year, to purchase the minimum quantity for the preceding marketing year on a product-by-product basis) or if Tuteur discontinues selling the products, after completing registration and obtaining required approvals, for longer than 45 days or 90 days or more in the event such discontinuation is caused due to a force majeure event. The agreement includes a mutual indemnification undertaking, standard confidentiality obligations and obligations of Tuteur to comply with anti-corruption and privacy laws. The agreement includes a non-compete undertaking of Tuteur during the term of the agreement and for a period of 12 months thereunder (other than in the event the agreement is terminated for cause by Tuteur due to our breach of the agreement).

Indemnification Agreements

We have entered into indemnification and exculpation agreements with each of our current officers and directors, exculpating them from a breach of their duty of care to us to the fullest extent permitted by the Companies Law (provided that we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law)) and undertaking to indemnify them to the fullest extent permitted by the Companies Law (other than indemnification for litigation expenses in connection with a monetary sanction), including with respect to liabilities resulting from our initial public offering in the United States, to the extent such liabilities are not covered by insurance. See "Item 6. Directors, Senior Management and Employees — Exculpation, Insurance and Indemnification of Office Holders."

Employment Agreements

We have entered into employment agreements with our executive officers and key employees, which are terminable by either party for any reason. The employment agreements contain standard provisions, including assignment of invention provisions and non-competition clauses. See "Item 6. Directors, Senior Management and Employees — Employment Agreements with Executive Officers."

Shareholders' Agreement

Under a shareholders' agreement entered into on March 4, 2013, the Recanati Group, on the one hand, and the Damar Group, on the other hand, have each agreed to vote the ordinary shares beneficially owned by them in favor of the election of director nominees designated by the other group as follows: (i) three director nominees, so long as the other group beneficially owns at least 7.5% of our outstanding share capital, (ii) two director nominees, so long as the other group beneficially owns at least 5.0% (but less than 7.5%) of our outstanding share capital, and (iii) one director nominee, so long as the other group beneficially owns at least 2.5% (but less than 5.0%) of our outstanding share capital. In addition, to the extent that after the designation of the foregoing director nominees there are additional director vacancies, each of the Recanati Group and Damar Group have agreed to vote the ordinary shares beneficially owned by them in favor of such additional director nominees designated by the party who beneficially owns the larger voting rights in our company.

FIMI Private Placement

On January 20, 2020, we entered into a securities purchase agreement with the FIMI Funds to purchase an aggregate of 4,166,667 ordinary shares at a price of $6.00 per share, for an aggregate $25 million gross proceeds. Concurrently, we entered into a registration rights agreement with the FIMI Funds, pursuant to which the FIMI Funds are entitled to customary demand registration rights (effective six months following the closing of the transaction) and piggyback registration rights with respect to our shares held by them. Upon the closing of the private placement, the beneficial ownership of the FIMI Funds increased from approximately 12.15% to 21.13%. Lilach Asher Topilsky, the Chairman of our board of directors, Ishay Davidi and Amiram Boehm, members of our board of directors, are partners of the FIMI Funds. For details regarding the beneficial ownership of the FIMI Funds and Messrs. Davidi and Boehm and Ms. Asher Topilsky see "Item 7. Major Shareholders and Related Party Transactions — Major Shareholders" and "Item 6. Directors, Senior Management and Employees — Share Ownership."

Engagements with Suppliers and Service Providers Affiliated with the FIMI Funds

We have entered into certain agreements in the ordinary course of our business for the purchase of certain products and services (such as security services, office equipment and recycling services) from entities controlled by or affiliated with the FIMI Funds, all of which were entered into prior to the FIMI Funds becoming a shareholder of our company and on an arm's length basis. These agreements include customary terms and conditions as applicable to the type of supplied product or services.

Item 8. Financial Information

Consolidated financial statements are set forth under Item 18.

Item 9. The Offer and Listing

Our ordinary shares are quoted on the Nasdaq Global Select Market and the TASE under the symbol "KMDA."

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

A copy of our amended and restated articles of association is attached as Exhibit 1.1 to this Annual Report. Other than as set forth below, the information called for by this Item is set forth in Exhibit 2.1 to this Annual Report and is incorporated by reference into this Annual Report.

Establishment and Purposes of the Company

We were incorporated under the laws of the State of Israel on December 13, 1990 under the name Kamada Ltd. We are registered with the Israeli Registrar of Companies in Jerusalem. Our registration number is 51-152460-5. Our purpose as set forth in our amended articles of association is to engage in any lawful business.

Shareholder Meetings

Under the Companies Law, we are required to convene an annual general meeting of our shareholders at least once every calendar year and within a period of not more than 15 months following the preceding annual general meeting. In addition, the Companies Law provides that our board of directors may convene a special general meeting of our shareholders whenever it sees fit and is required to do so upon the written request of (i) two directors or one quarter of the serving members of our board of directors, or (ii) one or more holders of 5% or more of our outstanding share capital and 1% of our voting power, or the holder or holders of 5% or more of our voting power.

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which, as a company listed on an exchange outside Israel, may be between four and 40 days prior to the date of the meeting. The Companies Law requires that resolutions regarding the following matters (among others) be approved by our shareholders at a general meeting: amendments to our articles of association; appointment, terms of service and termination of service of our auditors; election of external directors (if applicable); approval of certain related party transactions; increases or reductions of our authorized share capital; mergers; and the exercise of our board of director's powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is essential for our proper management.

The chairman of our board of directors presides over our general meetings. However, if at any general meeting the chairman is not present within 15 minutes after the appointed time, or is unwilling to act as chairman of such meeting, then the shareholders present will choose any other person present to be chairman of the meeting. Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which, as company listed also on an exchange outside of Israel, may be between four and 40 days prior to the date of the meeting.

Israeli law requires that a notice of any annual general meeting or special general meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes, among other things, the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, an approval of a merger or the approval of the compensation policy, notice must be provided at least 35 days prior to the meeting.

Borrowing powers

Pursuant to the Companies Law and our amended and restated articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our amended and restated articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

C. Material Contracts

We have not entered into any material contracts other than in the ordinary course of business and other than those described in "Item 4. Information on the Company" or elsewhere in this Annual Report.

D. Exchange Controls

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the ordinary shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of countries that are, or have been, in a state of war with Israel.

Non-residents of Israel who hold our ordinary shares are able to repatriate any dividends (if any), any amounts received upon the dissolution, liquidation and winding up of our affairs and proceeds of any sale of our ordinary shares, into non-Israeli currency at the rate of exchange prevailing at the time of conversion, provided that any applicable Israeli income tax has been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of exchange controls has not been eliminated, and may be restored at any time by administrative action.

E. Taxation

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

Israeli Tax Considerations and Government Programs

The following is a brief summary of the material Israeli tax laws applicable to us, and certain Israeli Government programs benefiting us. This section also contains a discussion of material Israeli tax consequences concerning the ownership of and disposition of our ordinary shares. This summary does not discuss all aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors, such as traders in securities, who are subject to special treatment under Israeli law. The discussion below is subject to amendment under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which could affect the tax consequences described below.

The discussion below does not cover all possible tax considerations. Potential investors are urged to consult their own tax advisors as to the Israeli or other tax consequences of the purchase, ownership and disposition of our ordinary shares, including in particular, the effect of any foreign, state or local taxes.

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax, which has decreased in recent years, from a rate of 25% in 2016 to 24% in 2017 and further decreased to 23% in 2018 and thereafter. However, the effective corporate tax rate payable by a company that derives income from an Approved Enterprise, a Privileged Enterprise or a Preferred Enterprise (as discussed below) may be considerably less. Capital gains generated by an Israeli company are generally subject to tax at the corporate tax rate.

Law for the Encouragement of Industry (Taxes), 1969

The Law for the Encouragement of Industry (Taxes), 1969 (the "Encouragement of Industry Law"), provides several tax benefits to "Industrial Companies." Pursuant to the Encouragement of Industry Law, a company qualifies as an Industrial Company if it is a resident of Israel and at least 90% of its income in any tax year (exclusive of income from certain defense loans) is generated from an "Industrial Enterprise" that it owns and is located in Israel or in the "Area", in accordance with its definition under section 3A of the Israeli Income Tax Ordinance. An Industrial Enterprise is defined as an enterprise whose principal activity, in a given tax year, is industrial activity.

An Industrial Company is entitled to certain tax benefits, including: (i) a deduction of the cost of purchases of patents and know-how and the right to use patents and know-how used for the development or promotion of the Industrial Enterprise in equal amounts over a period of eight years, beginning from the year in which such rights were first used, (ii) the right to elect to file consolidated tax returns, under certain conditions, with additional Israeli Industrial Companies controlled by it, and (iii) the right to deduct expenses related to public offerings in equal amounts over a period of three years beginning from the year of the offering.

Eligibility for benefits under the Encouragement of Industry Law is not contingent upon the approval of any governmental authority.

We believe that we may qualify as an Industrial Company within the meaning of the Encouragement of Industry Law; however, there is no assurance that we qualify or will continue to qualify as an Industrial Company or that the benefits described above will be available in the future.

Law for the Encouragement of Capital Investments, 1959

Our facilities in Israel were granted Approved Enterprise status under the Law for the Encouragement of Capital Investments, 1959, commonly referred to as the "Investment Law". The Investment Law provides that a capital investment in eligible production facilities (or other eligible assets) may, upon application to the Investment Center, be designated as an "Approved Enterprise." Each certificate of approval for an Approved Enterprise relates to a specific investment program delineated both by its financial scope, including its sources of capital, and by its physical characteristics, for example, the equipment to be purchased and utilized pursuant to the program. The tax benefits generated from any such certificate of approval relate only to taxable income attributable to the specific Approved Enterprise.

In recent years the Investment Law has undergone major reforms and several amendments which were intended to provide expanded tax benefits and to simplify the bureaucratic process relating to the approval of investments qualifying under the Investment Law. The different benefits under the Investment Law depend on the specific year in which the enterprise received approval from the Investment Center or the year it was eligible for Approved/Privileged/Preferred Enterprise status under the Investment Law, and the benefits available at that time. Below is a short description of the different benefits available to us under the Investment Law:

Approved Enterprise

One of our facilities was granted Approved Enterprise status by the Investment Center, which made us eligible for a grant and certain tax benefits under the "Grant Track." The approved investment program provided us with a grant in the amount of 24% of our approved investments, in addition to certain tax benefits, which applied to our turnover resulting from the operation of such investment program, for a period of up to ten consecutive years from the first year in which we generated taxable income. The tax benefits under the Grant Track include accelerated depreciation and amortization for tax purposes as well as a tax exemption for the first two years of the benefit period and the taxation of income generated from an Approved Enterprise at a reduced corporate tax rate of 10%-25% (depending on the level of foreign investment in each year), for a certain period of time. The benefit period is ordinarily seven to ten years commencing with the year in which the Approved Enterprise first generates taxable income. The benefit period is limited to 12 years from the earlier of the operational year as determined by the Investment Center or 14 years from the date of approval of the Approved Enterprise. The tax benefits under the Approved Enterprise status expired at the end of 2017.

Privileged Enterprise

We obtained a tax ruling from the Israel Tax Authority according to which, among other things, our activity has been qualified as an "industrial activity", as defined in the Investment Law and is also eligible to tax benefits as a Privileged Enterprise under the "Tax Benefit Track," which apply to the turnover attributed to such enterprise, for a period of up to ten years from the first year in which we generated taxable income.

On April 1, 2005, an amendment to the Investment Law came into effect (the "2005 Amendment"), which revised the criteria for investments qualified to receive tax benefits. An eligible investment program under the 2005 Amendment will qualify for benefits as a "Privileged Enterprise" (rather than the previous terminology of Approved Enterprise). Pursuant to the 2005 Amendment, a company whose facilities meet certain criteria set forth in the 2005 Amendment may claim certain tax benefits offered by the Investment Law (as further described below) directly in its tax returns, without the need to obtain prior approval. In order to receive the tax benefits, the company must make an investment in the Privileged Enterprise which meets all of the conditions, including exceeding a certain percentage or a minimum amount, specified in the Investment Law. Such investment must be made over a period of no more than three years ending at the end of the year in which the company requested to have the tax benefits apply to the Privileged Enterprise (the "Year of Election"). According to the tax ruling mentioned above, our Year of Election is 2009. We also elected 2012 as a Year of Election. The duration of tax benefits is subject to a limitation of the earlier of seven to ten years from the first year in which the company generated taxable income (at or after the Year of Election), or 12 years from the first day of the Year of Election. Therefore, the tax benefits under our Privileged Enterprise are scheduled to expire at the end of 2023.

The term "Privileged Enterprise" means an industrial enterprise which is "competitive" and contributes to the gross domestic product, and for which a minimum entitling investment was made in order to establish it (as explained above). For this purpose, an industrial enterprise is deemed to be competitive and contributing to the gross domestic product if it meets one of the following conditions: (1) its main activity is in the field of biotechnology or nanotechnology, as certified by the Director of the Industrial Research and Development Administration before the project was approved; or (2) its income during a tax year from sales to a certain market does not exceed 75% of its total income from sales in that tax year; or (3) 25% or more of its total income from sales in the tax year is from sales to a certain market with at least 14,000,000 inhabitants.

A taxpayer owning a Privileged Enterprise may be entitled to an exemption from corporate tax on undistributed income for a period of two to ten years, depending on the location of the Privileged Enterprise within Israel, as well as a reduced corporate tax rate of 10% to 25% for the remainder of the benefit period, depending on the level of foreign investment in each year. In addition, the Privileged Enterprise is entitled to claim accelerated depreciation for manufacturing assets used by the Privileged Enterprise.

However, a company that pays a dividend out of income generated during the tax exemption period from the Privileged/Approved Enterprise is subject to deferred corporate tax with respect to the otherwise exempt income (grossed-up to reflect the pre-tax income that we would have had to earn in order to distribute the dividend) at the corporate tax rate which would have applied if the company had not enjoyed the exemption (i.e. at a tax rate between 10% and 25%, depending on the level of foreign investment). A company is generally required to withhold tax on such distribution at a rate of 20% (or a reduced rate under an applicable double tax treaty, subject to the approval by the Israel Tax Authority).

Preferred Enterprise

An amendment to the Investment Law that became effective on January 1, 2011 ("Amendment No. 68") changed the benefit alternatives available to companies under the Investment Law and introduced new benefits for income generated by a "Preferred Company" through its "Preferred Enterprises" (as such terms are defined in the Investment Law). The definition of a Preferred Company includes a company incorporated in Israel that is not wholly-owned by a governmental entity, and that, among other things, owns a Preferred Enterprise and is controlled and managed from Israel. The tax benefits granted to a Preferred Company are determined depending on the location of its Preferred Enterprise within Israel. Amendment No. 68 imposes a reduced flat corporate tax rate which is not program-dependent and applies to the Preferred Company's "preferred income" which is generated by its Preferred Enterprise.

According to the Investment Law, a Preferred Company is subject to reduced corporate tax rate of 10% for preferred income attributed to Preferred Enterprises located in areas in Israel designated as Development Zone A and 15% for those located elsewhere in Israel in the tax years 2011-2012, and 7% for Development Zone A and 12.5% for the rest of Israel in the tax year 2013, and 9% for Development Zone A and 16% for the rest of Israel in the tax years 2014 until 2016. Under an amendment to the Investment Law that became effective on January 1, 2017, the corporate tax rate applying to income attributed to Preferred Enterprise located in Development Zone A was reduced to 7.5% while the reduced corporate tax rate for the rest of Israel remains 16%. Income derived by a Preferred Company from a "Special Preferred Enterprise" (as such term is defined in the Investment Law) would be entitled, during a benefits period of 10 years, to further reduced tax rates of 5% if the Special Preferred Enterprise is located in Development Zone A, or 8% if the Special Preferred Enterprise is located elsewhere in Israel.

The tax benefits under Amendment No. 68 also include accelerated depreciation and amortization for tax purposes during the first five-year period for productive assets that the Preferred Enterprise uses pursuant to the rates prescribed in the Investment Law. Preferred Enterprises located in specific locations within Israel (Development Zone A) are eligible for grants and/or loans approved by the Israeli Investment Center, as well as tax benefits. Our facility in Beit-Kama, Israel, is located in Development Zone A.

A dividend distributed from income which is attributed to a Preferred Enterprise/Special Preferred Enterprise will be subject to withholding tax at source at the following rates: (i) Israeli resident corporation – 0%, (ii) Israeli resident individual – 20% (iii) non-Israeli resident – 20% subject to a reduced tax rate under the provisions of an applicable double tax treaty.

The provisions of Amendment No. 68 do not apply to existing Privileged Enterprises or Approved Enterprises, which will continue to be entitled to the tax benefits under the Investment Law as in effect prior to Amendment No. 68. Nevertheless, a company owning such enterprises may choose to apply Amendment No. 68 to its existing enterprises while waiving benefits provided under the Investment Law as in effect prior to Amendment No. 68. Once a company elects to be classified as a Preferred Enterprise under the provisions of Amendment No. 68, the election cannot be rescinded and such company will no longer enjoy the tax benefits of its Approved/Privileged Enterprises.

To date, we have not elected to be classified as a Preferred Enterprise under Amendment No. 68.

Tax benefits under the 2017 Amendment that became effective on January 1, 2017

An amendment to the Investment Law was enacted as part of the Economic Efficiency Law that was published on December 29, 2016 and became effective as of January 1, 2017 (the "2017 Amendment"). The 2017 Amendment provides new tax benefits for two types of "Technology Enterprises", as described below, and is in addition to the other existing tax beneficial programs under the Investment Law.

The 2017 Amendment provides that a technology company satisfying certain conditions will qualify as a "Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 12% on income that qualifies as "Preferred Technology Income", as defined in the Investment Law. The tax rate is further reduced to 7.5% for a Preferred Technology Enterprise located in Development Zone A. In addition, a Preferred Technology Company will enjoy a reduced corporate tax rate of 12% on capital gain derived from the sale of certain "Benefitted Intangible Assets" (as defined in the Investment Law) to a related foreign company if the Benefitted Intangible Assets were acquired from a foreign company on or after January 1, 2017 for at least NIS 200 million, and the sale receives prior approval from the National Authority for Technological Innovation ("NATI").

The 2017 Amendment further provides that a technology company satisfying certain conditions will qualify as a "Special Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 6% on "Preferred Technology Income" regardless of the company's geographic location within Israel. In addition, a Special Preferred Technology Enterprise will enjoy a reduced corporate tax rate of 6% on capital gain derived from the sale of certain "Benefitted Intangible Assets" to a related foreign company if the Benefitted Intangible Assets were either developed by the Special Preferred Technology Enterprise or acquired from a foreign company on or after January 1, 2017, and the sale received prior approval from NATI. A Special Preferred Technology Enterprise that acquires Benefitted Intangible Assets from a foreign company for more than NIS 500 million will be eligible for these benefits for at least ten years, subject to certain approvals as specified in the Investment Law.

Dividends distributed by a Preferred Technology Enterprise or a Special Preferred Technology Enterprise, paid out of Preferred Technology Income, are generally subject to withholding tax at source at the rate of 20% or such lower rate as may be provided in an applicable tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for a reduced tax rate). However, if such dividends are paid to an Israeli company, no tax is required to be withheld. If such dividends are distributed to a foreign company and other conditions are met, the withholding tax rate will be 4%.

There can be no assurance that we will comply with the conditions required to remain eligible for benefits under the Investment Law in the future, including under our tax ruling with respect to our Privileged Enterprise, or that we will be entitled to any additional benefits thereunder. If we do not fulfill these conditions in whole or in part, the benefits can be canceled and we may be required to refund the amount of the benefits, linked to the Israeli consumer price index, with interest.

The Encouragement of Industrial Research, Development and Technological Innovation in the Industry Law, 5744-1984 (formerly known as The Encouragement of Industrial Research and Development Law, 5744-1984)

We have received grants from the Government of the State of Israel through the Israel Innovation Authority of the Israeli Ministry of Economy and Industry (the "IIA") (formerly known as the Office of the Chief Scientist of the Israeli Ministry of Economy (the "OCS")), for the financing of a portion of our research and development expenditures pursuant to the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Encouragement of Industrial and Development Law, 5744-1984) (the "Research Law") and related regulations. We previously received funding from the IIA for six research and development programs, in the aggregate amount of approximately $1.9 million as of December 31, 2020, which amount has accrued aggregate interest of approximately $8,252 as of such date, and we had paid aggregate royalties to the IIA for these programs in the amount of approximately $1.0 million and had a contingent liability to the IIA in the amount of approximately $0.9 million (excluding any interest thereon) as of December 31, 2020.

Under the Research Law, research and development programs which meet specified criteria and are approved by the IIA (formerly the OCS) are eligible for grants. Under the Research Law, as currently in effect, the grants awarded are typically up to 50% of the project's expenditures. The grantee is required to pay royalties to the State of Israel from the sale of products developed under the program. Regulations under the Research Law, as currently in effect, generally provide for the payment of royalties of 3% to 5% on sales of products and services based on technology developed using grants, until 100% (which may be increased under certain circumstances) of the U.S. dollar-linked value of the grant is repaid, with interest at the rate of 12-month LIBOR. The terms of the IIA grants generally require that products developed with such grants be manufactured in Israel and that the technology developed thereunder may not be transferred outside of Israel, unless approval is received from the IIA and additional payments are made to the State of Israel. However, this does not restrict the export of products that incorporate the funded technology. The royalty repayment ceiling can reach up to three times the amount of the grant received if manufacturing is moved outside of Israel, and if the funded technology itself is transferred outside of Israel, the royalty ceiling can reach up to six times the amount of grants (plus interest). Even following the full repayment of any IIA grants, we must nevertheless continue to comply with the requirements of the Research Law. If we fail to comply with any of the conditions and restrictions imposed by the Research Law, or by the specific terms under which we received the grants, we may be required to refund any grants previously received together with interest and penalties, and, in certain circumstances, may be subject to criminal charges.

Taxation of Our Shareholders

The Israeli Income Tax Ordinance applies Israeli tax on a worldwide basis with respect to Israeli residents, and on an Israeli source income, with respect to non-Israeli residents. Dividends distributed (or deemed distributed) by an Israeli resident company to a holder in respect of its securities and consideration received by a holder (or deemed received) in connection with the sale or other disposition of securities of an Israeli resident company are considered to be an Israeli source income.

Capital Gains

Under present Israeli tax legislation, the tax rate applicable to real capital gain derived by Israeli resident corporations from the sale of shares of an Israeli company is the general corporate tax rate (which was 25% in 2016, reduced to 24% in 2017 and further reduced to 23% in 2018 and thereafter).

Generally, as of January 1, 2006, the tax rate applicable to real capital gain derived by Israeli individuals from the sale of shares which had been purchased on or after January 1, 2003, whether or not listed on a stock exchange, is 25%, unless such shareholder claims a deduction for interest and linkage differences expenses in connection with the purchase and holding of such shares. Additionally, if such a shareholder is considered a "Substantial Shareholder" (*i.e.,* a person who holds, directly or indirectly, alone or together with another, 10% or more of any of the company's "means of control" (including, among other things, the right to receive profits of the company, voting rights, the right to receive the company's liquidation proceeds and the right to appoint a director)) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30%. Individual shareholders dealing in securities in Israel are taxed at their marginal tax rates applicable to business income (up to 47% from 2017).

Notwithstanding the foregoing, capital gains generated from the sale of shares by a non-Israeli shareholder may be exempt from Israeli taxes provided that, in general, both the following conditions are met: (i) the seller of the shares does not have a permanent establishment in Israel to which the generated capital gain is attributed and (ii) if the seller is a corporation, less than 25% of its means of control are held, directly and indirectly, by Israeli residents or Israeli residents that are the beneficiaries or are eligible to less than 25% of the seller's income or profits from the sale. In addition, the sale of the shares may be exempt from Israeli capital gain tax under the provisions of an applicable tax treaty. For example, the Convention between the Government of the United States of America and the Government of Israel with respect to Taxes on Income, or the "Israel-U.S.A. Double Tax Treaty," generally exempts U.S. residents from Israeli capital gains tax in connection with such sale, provided that (i) the U.S. resident owned, directly or indirectly, less than 10% of the Israeli resident company's voting power at any time within the 12-month period preceding such sale; (ii) the seller, if an individual, has been present in Israel for less than 183 days (in the aggregate) during the taxable year; and (iii) the capital gain from the sale was not generated through a permanent establishment of the U.S. resident in Israel.

The purchaser of the shares, the stockbrokers who effected the transaction or the financial institution holding the shares through which payment to the seller is made are obligated, subject to the above-referenced exemptions if certain conditions are met, to withhold tax on the real capital gain resulting from a sale of shares at the rate of 25%.

A detailed return, including a computation of the tax due, must be filed and an advance payment must be paid on January 31 and July 31 of each tax year for sales of shares traded on a stock exchange made within the six months preceding the month of the report. However, if the seller is exempt from tax or all tax due was withheld at the source according to applicable provisions of the Israeli Income Tax Ordinance and the regulations promulgated thereunder, the return does not need to be filed and an advance payment does not need to be made. Taxable capital gains are also reportable on an annual income tax return if applicable.

Dividends

Our company is obligated to withhold tax, at the rate of 20%, upon the distribution of a dividend attributed to an Approved/Privileged Enterprise's income, subject to a reduced tax rate under the provisions of an applicable double tax treaty, provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance. If the dividend is distributed from income not attributed to an Approved/Privileged Enterprise, the following withholding tax rates will apply: (i) Israeli resident corporations — 0%, (ii) Israeli resident individuals — 25% (or 30% in the case of a Substantial Shareholder) and (iii) non-Israeli residents (whether an individual or a corporation), so long as the shares are registered with a nominee company — 25%, subject to a reduced tax rate under the provisions of an applicable double tax treaty, provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance. Generally, unless the recipient of the dividend is a U.S. corporate resident which holds at least 10% of the share capital of the Company, the withholding rate will not be reduced under the Israel-U.S.A. Double Tax Treaty.

Excess Tax

An additional tax liability at the rate of 3% in 2017 onwards is added to the applicable tax rate on the annual taxable income of individuals (whether any such individual is an Israeli resident or non-Israeli resident) exceeding NIS 649,560 in 2019, NIS 651,600 in 2020 and NIS 647,640 in 2021.

Estate and gift tax

Israeli law presently does not impose estate or gift taxes.

United States Federal Income Taxation

The following is a description of the material U.S. federal income tax consequences to a U.S. Holder (as defined below) of the acquisition, ownership and disposition of our ordinary shares. This description addresses only the U.S. federal income tax consequences to holders of our ordinary shares in the United States that will hold our ordinary shares as capital assets for U.S. federal income tax purposes. This description does not address many of the tax considerations applicable to holders that may be subject to special tax rules, including, without limitation:

- banks, certain financial institutions or insurance companies;
- real estate investment trusts, regulated investment companies or grantor trusts;
- dealers or traders in securities, commodities or currencies;
- tax-exempt entities;
- certain former citizens or long-term residents of the United States;
- persons that received our shares as compensation for the performance of services;
- persons that will hold our shares as part of a "hedging," "integrated" or "conversion" transaction or as a position in a "straddle" for U.S. federal income tax purposes;
- partnerships (including entities classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or holders that will hold our shares through such an entity;

- S-corporations;
- persons whose "functional currency" is not the U.S. Dollar;
- persons that own directly, indirectly or through attribution 10% or more of the voting power or value of our shares; or
- persons holding our ordinary shares in connection with a trade or business conducted outside the United States.

Moreover, this description does not address the U.S. federal estate, gift or alternative minimum tax consequences, or any state, local or foreign tax consequences, of the acquisition, ownership and disposition of our ordinary shares.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, (the "Code"), existing, proposed and temporary U.S. Treasury Regulations and judicial and administrative interpretations thereof, in each case as in effect on the date hereof. All of the foregoing is subject to change, which change could apply retroactively and could affect the tax consequences described below. There can be no assurance that the U.S. Internal Revenue Service ("IRS") will not take a different position concerning the tax consequences of the acquisition, ownership and disposition of our ordinary shares or that the IRS's position would not be sustained.

For purposes of this description, a "U.S. Holder" is a beneficial owner of our ordinary shares that, for U.S. federal income tax purposes, is:

- a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any jurisdiction thereof; or
- a trust or estate the income of which is subject to United States federal income taxation regardless of its source.

Holders should consult their tax advisors with respect to the U.S. federal, state, local and foreign tax consequences of acquiring, owning and disposing of our ordinary shares.

Distributions

Subject to the discussion below under "Passive Foreign Investment Company Considerations," the gross amount of any distribution made to a U.S. Holder with respect to our ordinary shares before reduction for any Israeli taxes withheld therefrom, other than certain pro rata distributions of our ordinary shares to all our shareholders, generally will be includible in the U.S. Holder's income as dividend income to the extent the distribution is paid out of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. Subject to the discussion below under "Passive Foreign Investment Company Considerations," non-corporate U.S. Holders may qualify for the lower rates of taxation with respect to dividends on ordinary shares applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) provided that certain conditions are met, including certain holding period requirements and the absence of certain risk reduction transactions. However, dividends on our ordinary shares will not be eligible for the dividends received deduction generally allowed to corporate U.S. Holders. Subject to the discussion below under "Passive Foreign Investment Company Considerations," to the extent that the amount of any distribution by us exceeds our current and accumulated earnings and profits as determined under U.S. federal income tax principles, it will be treated first as a tax-free return of tax basis in our ordinary shares and thereafter as capital gain. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles and, therefore, U.S. Holders should expect that the entire amount of any distribution generally will be reported as dividend income.

Dividends paid to U.S. Holders with respect to our ordinary shares will be treated as foreign source income, which may be relevant in calculating a U.S. Holder's foreign tax credit limitation. Subject to certain conditions and limitations, Israeli tax withheld on dividends may be deducted from taxable income or credited against U.S. federal income tax liability. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends that we distribute generally should constitute "passive category income," or, in the case of certain U.S. Holders, "general category income." A foreign tax credit for foreign taxes imposed on distributions may be denied if certain minimum holding period requirements are not satisfied. The rules relating to the determination of the foreign tax credit are complex, and U.S. Holders should consult their tax advisors to determine whether and to what extent they will be entitled to this credit.

Sale, Exchange or Other Disposition of Ordinary Shares

Subject to the discussion below under "Passive Foreign Investment Company Considerations," U.S. Holders generally will recognize gain or loss on the sale, exchange or other disposition of our ordinary shares equal to the difference between the amount realized on the sale, exchange or other disposition and the holder's tax basis in our ordinary shares, and any gain or loss will be capital gain or loss. The tax basis in an ordinary share generally will be equal to the cost of the ordinary share. For non-corporate U.S. Holders, capital gain from the sale, exchange or other disposition of ordinary shares is generally eligible for a preferential rate of taxation in the case of long-term capital gain. The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations under the Code. Any gain or loss that a U.S. Holder recognizes generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes.

Passive Foreign Investment Company Considerations

If we were to be classified as a "passive foreign investment company" ("PFIC") in any taxable year, a U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules, either

- at least 75% of its gross income is "passive income", or
- at least 50% of the average quarterly value of its gross assets is attributable to assets that produce passive income or are held for the production of passive income.

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income and amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as directly receiving its proportionate share of the other corporation's income. If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our ordinary shares, we generally will continue to be treated as a PFIC with respect to that U.S. Holder in all succeeding years during which the U.S. Holder owns our ordinary shares, regardless of whether we continue to meet the tests described above.

However, our PFIC status for each taxable year may be determined only after the end of such year and will depend on the composition of our income and assets, our activities and the value of our assets (which may be determined in large part by reference to the market value of our ordinary shares, which may be volatile) from time to time. If we are a PFIC then unless a U.S. Holder makes one of the elections described below, a special tax regime will apply to both (i) any "excess distribution" by us to that U.S. Holder (generally, the U.S. Holder's ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by the holder in the shorter of the three preceding years or its holding period for our ordinary shares) and (ii) any gain realized on the sale or other disposition of the ordinary shares.

Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (i) the excess distribution or gain had been realized ratably over the U.S. Holder's holding period, (ii) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for that year (other than income allocated to the current period or any taxable period before we became a PFIC, which will be subject to tax at the U.S. Holder's regular ordinary income rate for the current year and will not be subject to the interest charge discussed below), and (iii) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to a U.S. Holder will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "Distributions." Certain elections may be available that would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares. We do not intend to provide the information necessary for U.S. Holders to make qualified electing fund elections if we are classified as a PFIC. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. Holders described in this paragraph would apply to indirect distributions and gains deemed to be realized by U.S. Holders in respect of any of our subsidiaries that also may be determined to be PFICs.

In addition, all U.S. Holders may be required to file tax returns (including on IRS Form 8621) containing such information as the U.S. Treasury may require. For example, if a U.S. Holder owns ordinary shares during any year in which we are classified as a PFIC and the U.S. Holder recognizes gain on a disposition of our ordinary shares or receives distributions with respect to our ordinary shares, the U.S. Holder generally will be required to file an IRS Form 8621 with respect to the company, generally with the U.S. Holder's federal income tax return for that year. The failure to file this form when required could result in substantial penalties.

Based on the financial information currently available to us and the nature of our business, we do not expect that we will be classified as a PFIC for the taxable year ended December 31, 2020. However, this determination could be subject to change. If, contrary to our expectations, we were to be classified as a PFIC, U.S. Holders of ordinary shares may be required to file form 8621 with respect to their ownership of our ordinary shares in the year in which we were a PFIC. U.S. Holders of our ordinary shares should consult their tax advisors in this regard.

Backup Withholding and Information Reporting Requirements

U.S. backup withholding and information reporting requirements may apply to payments to holders of our ordinary shares. Information reporting generally will apply to payments of dividends on, and to proceeds from the sale of, our ordinary shares made within the United States, or by a U.S. payor or U.S. middleman, to a holder of our ordinary shares, other than an exempt recipient (including a corporation). A payor may be required to backup withhold from payments of dividends on, or the proceeds from the sale or redemption of, ordinary shares within the United States, or by a U.S. payor or U.S. middleman, to a holder, other than an exempt recipient, if the holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, the backup withholding tax requirements. Any amounts withheld under the backup withholding rules generally should be allowed as a credit against the beneficial owner's U.S. federal income tax liability, if any, and any excess amounts withheld under the backup withholding rules may be refunded, provided that the required information is timely furnished to the IRS.

Additional Medicare Tax

Certain U.S. Holders who are individuals, estates or trusts may be required to pay an additional 3.8% Medicare tax on, among other things, dividends and capital gains from the sale or other disposition of shares of common stock. For individuals, the additional Medicare tax applies to the lesser of (i) "net investment income" or (ii) the excess of "modified adjusted gross income" over $200,000 ($250,000 if married and filing jointly or $125,000 if married and filing separately). "Net investment income" generally equals the taxpayer's gross investment income reduced by the deductions that are allocable to such income. U.S. Holders will likely not be able to credit foreign taxes against the 3.8% Medicare tax.

Foreign Asset Reporting

Certain U.S. Holders who are individuals (and certain domestic entities) may be required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions). U.S. Holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of our ordinary shares.

The above description is not intended to constitute a complete analysis of all tax consequences relating to acquisition, ownership and disposition of our ordinary shares. Holders should consult their tax advisors concerning the tax consequences of their particular situations.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to certain of the reporting requirements of Exchange Act, as applicable to "foreign private issuers" as defined in Rule 3b-4 under the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding registrants like us that file electronically with the SEC. You can also inspect the Annual Report on that website.

A copy of each document (or a translation thereof to the extent not in English) concerning our company that is referred to in this Annual Report is available for public view (subject to confidential treatment of certain agreements pursuant to applicable law) at our principal executive offices.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We are exposed to changes in interest arising from our financial assets as our financial debt bears fixed interest rates. We invest our cash balance in interest-bearing deposits. We have exposure to investments in deposits or securities bearing fixed interest, which expose us to interest rate risk with respect to fair value.

Foreign Currency Risk

Fluctuations in exchange rates, especially the NIS against the U.S. dollar, may affect our results, as part of our assets is linked to NIS, as are part of our liabilities. Changes in exchange rates may also affect the prices of products purchased by us and designated for marketing in Israel in cases where these product prices are not linked to the U.S. dollar and during the period after these products are sold to our customers in NIS. In addition, the fluctuation in the NIS exchange rate against the U.S. dollar may impact our results, as a portion of our manufacturing cost is NIS denominated.

For the years ended December 31, 2020, 2019 and 2018, we have witnessed high volatility in the U.S. dollar exchange rate. This fact impacts our revenues from the Distribution segment, where prices are denominated in or linked to the NIS upon delivery of product while our expenses for the purchase of raw materials and imported goods in the Distribution segment are in U.S. dollars and part of our development and marketing expenses are paid in NIS.

We attempt to mitigate our currency exposure by matching assets denominated in NIS currency with liabilities denominated in NIS. In the Distribution segment, we attempt to mitigate foreign currency exposure by matching Euro denominated expenses with Euro denominated revenues. Additionally, we used, and from time to time, will continue to use, currency hedging transactions using financial derivatives and forward currency contracts. We attempt to enter into forward currency contracts with critical terms that match those of the underlying exposure. As of December 31, 2020, we had open transactions in derivatives in the amount of approximately $0.3 million. We regularly monitor and review the need for currency hedging transactions in accordance with trend analysis.

The following table presents information about the changes in the exchange rates of the NIS against the U.S. dollar:

Period	Change in Average Exchange Rate of the NIS against the U.S. Dollar (%)
Year ended December 31, 2018	8.1
Year ended December 31, 2019	(7.8)
Year ended December 31, 2020	(7.0)

As of December 31, 2020, we had excess liabilities over assets denominated in NIS in the amount of $4.0 million. When the U.S. dollar appreciates against the NIS, we recognize financial expenses with respect to exchange rate differences. When the U.S. dollar devalues against the NIS, we recognize financial income.

As of December 31, 2020, we had foreign currency exposures to currencies other than U.S. dollars (mainly in EUR) amounting to $5.0 million in excess liabilities over assets. Most of this exposure is to the Euro.

A 10% increase (decrease) in the value of the NIS against the U.S. dollar would have decreased (increased) our financial assets by $0.4 million, $0.05 million and $1.2 million as of December 31, 2020, 2019 and 2018, respectively.

Item 12. Description of Securities Other Than Equity Securities

Not applicable.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Initial Public Offering

On June 5, 2013, we completed an initial public offering in the United States on Nasdaq of our ordinary shares, par value NIS 1.00 per share, pursuant to a Registration Statement on Form F-1, as amended (File No. 333-187870), which became effective on May 30, 2013. Morgan Stanley& Co. LLC and Jefferies LLC acted as representatives of the underwriters. We registered 5,582,636 ordinary shares in the offering and granted the underwriters a 30-day over-allotment option to purchase up to 837,395 additional ordinary shares from us. The option to purchase additional ordinary shares was exercised in full on June 4, 2013.

Pursuant to the initial public offering, we sold a total of 6,420,031 ordinary shares (including the shares sold pursuant to the over-allotment option) at a price of $9.25 per share. The aggregate offering price of the shares sold (including the over-allotment option) was approximately $59.4 million. The total expenses of the offering, including underwriting discounts and commissions, were approximately $6.6 million. The net proceeds we received from the offering (including the over-allotment option) were approximately $52.8 million. We paid a one-time management compensation payment associated with the initial public offering of approximately $1.1 million.

As of December 31, 2020, we have used a significant portion of the net proceeds of our initial public offering. We intend to use the remaining net proceeds we received from our initial public offering as disclosed in our Registration Statement on Form F-1.

Item 15. Controls and Procedures

(a) *Disclosure Controls and Procedures*. Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020, pursuant to Rule 13a-15 under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer (the principal executive and principal financial officer, respectively) have concluded that our disclosure controls and procedure are effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

(b) *Report* of *Management on Internal Control over Financial Reporting*. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our management has assessed the effectiveness of internal control over financial reporting based on the Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, our management has concluded that our internal control over financial reporting as of December 31, 2020 was effective.

(c) *Attestation Report of the Registered Public Accounting Firm*. Our independent registered public accounting firm, Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, has audited the consolidated financial statements included in this annual report on Form 20-F, and as part of its audit, has issued its audit report on the effectiveness of our internal control over financial reporting as of December 31, 2020. The report of Kost Forer Gabbay & Kasierer is included with our consolidated financial statements included elsewhere in this annual report and is incorporated herein by reference.

(d) *Changes in Internal Control over Financial Reporting*. During the period covered by this report, we have not made any changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert

Our board of directors has determined that Avraham Berger is an "independent" director for purposes of serving on an audit committee under the Exchange Act and Nasdaq listing requirements and qualifies as an "audit committee financial expert," as defined in Item 407(d)(5) of Regulation S-K.

Item 16B. Code of Ethics

We have adopted a Code of Ethics, which applies to our directors, officers and employees, including our Chief Executive Officer and Chief Financial Officer, principal accounting officer or controller, and persons performing similar functions. The Code of Ethics is posted on our website, www.kamada.com.

Item 16C. Principal Accountant Fees and Services

During the years ended December 31, 2020 and 2019, we were billed the following aggregate fees for the professional services rendered by Kost Forer Gabbay& Kasierer, a member of Ernst & Young Global, independent registered public accounting firm, all of which were pre-approved by our Audit Committee:

	Year Ended December 31,	
	2020	**2019**
Audit Fees (1)	$ 220,000	$ 245,000
Tax Fees (2)	27,453	10,000
All Other Fees (3)	-	72,027
Total	$ 247,453	$ 327,027

(1) Audit fees are aggregate fees for audit services for each of the years shown in this table, including fees associated with the annual audit and reviews of our quarterly financial results submitted on Form 6-K, the auditor attestation report on the effectiveness of our internal control over financial reporting, consultations on various accounting issues and audit services provided in connection with other statutory or regulatory filings.

(2) Tax services rendered by our auditors in 2020 and 2019 were for compliance with tax regulation.

(3) Other fees in 2019 mainly include services in connection with risk analysis, SEC correspondence and policy implementation of new regulation.

Our audit committee has adopted a policy for pre-approval of audit and non-audit services provided by our independent auditor. Under the policy, such services must require the specific pre-approval of our audit committee followed by ratification of our full board of directors. Any proposed services exceeding the pre-approval amounts for all services to be provided by our independent auditor require an additional specific pre-approval by our audit committee.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchase of Equity Securities by the Issuer and Affiliated Purchasers

In the year ended December 31, 2020, neither we nor any affiliated purchaser (as defined in the Exchange Act) purchased any of our ordinary shares.

Item 16F. Change in Registrant's Certifying Accountant

None.

Item 16G. Corporate Governance

As a foreign private issuer whose shares are listed on the Nasdaq Global Select Market, we have the option to follow Israeli corporate governance practices rather than certain of those of Nasdaq, except to the extent that such laws would be contrary to U.S. securities laws and provided that we disclose the practices we are not following and describe the home country practices we follow instead. We rely on this "foreign private issuer exemption" with respect to the following Nasdaq requirements:

- *Shareholder approval requirements for equity issuances and equity-based compensation plans.* Under the Companies Law, the adoption of, and material changes to, equity-based compensation plans generally require the approval of the board of directors (for approval of equity based arrangements, see "Item 6. Directors, Senior Management and Employees — Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law — Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions," "Item 6. Directors, Senior Management and Employees — Compensation of Directors" and "Item 6. Directors, Senior Management and Employees — Compensation of Executive Officers"). Similarly, the approval of the board of directors is generally sufficient for a private placement unless the private placement is deemed a "significant private placement" (see "Item 6. Directors, Senior Management and Employees — Approval of Significant Private Placements"), in which case shareholder approval is also required, or an office holder or a controlling shareholder or their relative has a personal interest in the private placement, in which case, audit committee approval is required prior to the board approval and, for a private placement in which a controlling shareholder or its relative has a personal interest, shareholder approval is also required (see "Item 6. Directors, Senior Management and Employees — Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law").

- *Requirement for independent oversight on our director nominations process and to adopt a formal written charter or board resolution addressing the nominations process.* In accordance with Israeli law and practice, directors are recommended by our board of directors for election by our shareholders. The Damar Group and Recananti Group have entered into a shareholders' agreement which includes an agreement about voting in the election of nominees appointed by the other party (see "Item 7. Major Shareholders and Related Party Transactions — Related Party Transactions — Shareholders' Agreement").

- *Quorum requirement.* Under our articles of association and as permitted under the Companies Law, a quorum for any meeting of shareholders shall be the presence of at least two shareholders present in person, by proxy or by a voting instrument, who hold at least 25% of the voting power of our shares instead of 33 1/3% of the issued share capital required under Nasdaq requirements. At an adjourned meeting, any number of shareholders shall constitute a quorum.

- *Compensation Committee Charter*. As permitted under the Companies Law, we do not have a formal charter for our compensation committee.

Except as stated above, we comply with the rules generally applicable to U.S. domestic companies listed on Nasdaq. We may in the future decide to use other foreign private issuer exemptions with respect to some or all of the other Nasdaq listing requirements. Following our home country governance practices, as opposed to the requirements that would otherwise apply to a company listed on Nasdaq, may provide less protection than is accorded to investors under Nasdaq listing requirements applicable to domestic issuers. For more information, see "Item 3. Key Information —D. Risk Factors — As we are a 'foreign private issuer' and intend to follow certain home country corporate governance practices, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all Nasdaq corporate governance requirements." We are also required to comply with Israeli corporate governance requirements under the Companies Law applicable to Israeli public companies, such as us, whose shares are listed for trade on an exchange outside Israel and dual listed on the TASE.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

Consolidated Financial Statements are set forth under Item 18.

Item 18. Financial Statements

Our Consolidated Financial Statements beginning on pages F-1 through F-72, as set forth in the following index, are hereby incorporated herein by reference. These Consolidated Financial Statements are filed as part of this Annual Report.

Item 19. Exhibits

Exhibit No.	Description
1.1	Amended Articles of Association of the Registrant (incorporated by reference to Appendix A2 to the Proxy Statement for the 2016 Annual General Meeting of Shareholders, filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on July 26, 2016).
1.2	Memorandum of Association of the Registrant, as currently in effect (as translated from Hebrew) (incorporated by reference to Exhibit 3.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
2.1	Description of Securities (incorporated by reference to Exhibit 2.1 of the Annual Report on Form 20-F/A filed with the Securities and Exchange Commission on March 16, 2020)
2.2	Form of Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.1†	Exclusive Manufacturing, Supply and Distribution Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.2†	Technology License Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare S.A. (incorporated by reference to Exhibit 10.2 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.3†	Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.3 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.4†	First Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of May 10, 2011, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.4 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.5†	Second Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of June 22, 2011, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.5 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.6†	License Agreement, dated as of November 16, 2006, by and between PARI GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.7 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.7†	Amendment No. 1 to License Agreement, dated as of August 9, 2007, by and between PARI GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.8 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.8†	Addendum No. 1 to License Agreement, dated as of February 21, 2008, by and between PARI Pharma GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.9 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.9†	Supply and Distribution Agreement, dated as of July 18, 2011, by and between Kamada Ltd. and Kedrion S.p.A. (incorporated by reference to Exhibit 10.10 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.10	English translation of form of Indemnification Agreement with the Registrant's directors and officers (incorporated by reference to Exhibit 10.15 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.11	English translation of amendment to form of Indemnification Agreement with the Registrant's directors and officers (incorporated by reference to Appendixes A3 and A4 of the Proxy filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on May 22, 2015).
4.12	English summary of two lease agreements dated June 20, 2002, by and between the Israel Lands Administration and Kamada Nehasim (2001) Ltd., as such agreements were amended by lease agreement dated January 30, 2011, by and between the Israel Lands Authority and Kamada Assets (2001) Ltd. (incorporated by reference to Exhibit 10.16 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.13†	Fraction IV-1 Paste Supply Agreement, dated December 3, 2012, by and between Baxter Healthcare S.A. and Kamada Ltd. (incorporated by reference to Exhibit 10.18 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.14	Side Letter Agreement, dated as of March 23, 2011, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.20 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.15	First Amendment to the Exclusive Manufacturing Supply and Distribution Agreement, dated as of September 6, 2012, between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.21 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.16†	Second Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of May 14, 2013, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.22 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).

4.17†	First Amendment to the Technology License Agreement, dated as of May 14, 2013, by and between Kamada Ltd. and Baxter Healthcare SA (incorporated by reference to Exhibit 10.23 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 28, 2013).
4.18†	Third Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of September 2014, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 4.25 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 28, 2015).
4.19†	Third Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement executed on July 19, 2015 by and between Kamada Ltd. and Baxalta U.S. Inc. (incorporated by reference to Exhibit 4.29 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.20†	Fourth Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of October, 2015, by and between Kamada Ltd. and Baxalta U.S. Inc. (incorporated by reference to Exhibit 4.30 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.21†	Second Amendment to the Technology License Agreement, dated as of August 25, 2015, by and between Kamada Ltd. and Baxalta GmbH. (incorporated by reference to Exhibit 4.31 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.22†	Fifth Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of October 5, 2016, by and between Kamada Ltd. and Shire plc. (incorporated by reference to Exhibit 4.28 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 1, 2017).
4.23	Compensation Policy for Executive Officers (incorporated by reference to Appendix A1 to the Proxy Statement for the 2020 Annual General Meeting of Shareholders, filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on October 29, 2020).
4.24	Compensation Policy for Directors (incorporated by reference to Appendix A2 to the Proxy Statement for the 2020 Annual General Meeting of Shareholders, filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on October 29, 2020).
4.25†	Kamada Ltd. 2011 Israeli Share Award Plan (incorporated by reference to Exhibit 4.2 to the Form S-8 filed with the Securities and Exchange Commission on February 9, 2017).
4.26†	1st Addendum to Supply And Distribution Agreement dated October 15, 2016 between Kamada Ltd., and Kedrion S.p.A. (incorporated by reference to Exhibit 4.32 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 1, 2017).
4.27†	2nd Addendum to Supply And Distribution Agreement dated October 11, 2018 between Kamada Ltd., and Kedrion S.p.A. (incorporated by reference to Exhibit 4.29 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 27, 2019).
4.28†	Sixth Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of August 30, 2019, by and between Kamada Ltd. and Baxalta U.S. Inc. (incorporated by reference to Exhibit 4.30 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2020).
4.29†	Clinical Study Supply Agreement, dated as of May 5, 2019, by and between PARI GmbH and Kamada Ltd. (incorporated by reference to Exhibit 4.31 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2020).
4.30†	Binding Term Sheet between partner and Kamada Ltd., dated December 6, 2019 (incorporated by reference to Exhibit 4.32 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2020).
4.31	Share Purchase Agreement dated as of January 20, 2020, by and among Kamada Ltd. and the FIMI Funds (incorporated by reference to Exhibit 99.2 to Form 6-K filed with the Securities and Exchange Commission on January 21, 2020).
4.32	Registration Rights Agreement, dated as of January 20, 2020, by and among Kamada Ltd. and the FIMI Funds (incorporated by reference to Exhibit 99.3 to Form 6-K filed with the Securities and Exchange Commission on January 21, 2020).
4.33†	Distribution Agreement, dated as of May 20, 2020, by and between Kamada Ltd. and TUTEUR S.A.C.I.F.I.A.
4.34†	Binding Term Sheet, dated as of April 27, 2020, between Kamada Ltd. and Kedrion S.p.A.
4.35	Asset Purchase Agreement, dated January 31, 2021, by and among Kamada Plasma, LLC and Blood and Plasma Research, Inc
8.1	Subsidiaries of the Registrant.
12.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a).
12.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a).
13.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1	Consent of Ernst & Young Global, independent registered public accounting firm.

† Portions of this exhibit have been omitted.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

KAMADA LTD.

By: /s/ Chaime Orlev
Chaime Orlev
Chief Financial Officer

Date: February 24, 2021

Kamada Ltd.

Consolidated Financial Statements as of December 31, 2020

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REPORT OF INDEPENDENCE REGISTERED PUBLIC ACCOUNTING FIRM
To the Shareholders and the Board of Directors of

Kamada Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Kamada Ltd. and subsidiaries (the "Company") as of December 31, 2020 and 2019 the related consolidated statements of profit or loss and other comprehensive income, consolidated statements of changes in equity, and consolidated statements of cash flows, for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2020, in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standard Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework and our report dated February 24, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

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Valuation of Inventory

Description of the Matter

As of December 31, 2020, the Company's inventory totaled $42 million. As described in Note 2 to the consolidated financial statements, inventory is comprised of raw materials, work-in-progress, and finished goods relating to both the Proprietary and Distribution segments. The value of work in progress and finished goods related to the Proprietary segment includes direct and indirect costs. The allocation of indirect costs is accounted for on a quarterly basis by dividing the total quarterly indirect manufacturing cost to the number of batches manufactured during that quarter based on predetermined allocation factors.

The Company determines a standard manufacturing capacity for each quarter. To the extent the actual manufacturing capacity in a given quarter is lower than the predetermined standard, a portion of the indirect costs which is equal to the product of the overall quarterly indirect costs multiplied by the quarterly manufacturing shortfall rate is recognized as costs of revenues.

In addition, and as part of the quarterly inventory valuation process, the Company assesses the potential effect on inventory in cases of deviations from quality standards in the manufacturing process to identify potential required inventory write offs.

Auditing the valuation of the Company's inventory was complex and involved subjective auditor judgment because of the significant assumptions management makes to determine the standard manufacturing capacity and inventory write-off as a result from deviations from quality standards. In particular, the determination of the standard manufacturing capacity is subject to significant assumptions such as expected demand for the Company's products, expected industry sales growth and manufacturing schedules. Management's determination of deviations from quality standards is based on qualitative assessment, historical data and the Company's past experience.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated, and tested the design and operating effectiveness of internal controls over the Company's inventory valuation process, including controls over the determination of standard manufacturing capacities, the assessment of required write offs due to deviations from quality standards, and the completeness and accuracy of underlying data and assumptions.

To test management's determination of standard manufacturing capacities, our substantive audit procedures included, among others, evaluating the significant assumptions stated above by reading, on a sample bases, contracts with customers to review management's assessment of the expected demands for the Company's products, comparing the historical projections to actual operating results and testing the accuracy and completeness of the underlying data. We also evaluated whether manufacturing schedules were appropriate in comparison with the Company's historical data.

To test management's assessment of required write offs due to deviation from quality standards, our audit procedures included, among others, obtaining the deviations analysis reports from management and evaluating their appropriateness by comparing with historical data. We also held discussions with Company personnel to understand the judgments and qualitative factors considered in their analysis and compared the analysis reports with evidence obtained in other areas of the audit.

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

We have served as the Company's auditor since 2005.
Tel-Aviv, Israel
February 24, 2021

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of KAMADA LTD.

Opinion on Internal Control Over Financial Reporting

We have audited Kamada Ltd and subsidiaries' internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, Kamada Ltd. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Consolidated Statements of Financial Position of the Company as of December 31, 2020 and 2019, the related consolidated statements of comprehensive income, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated February 24, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

Tel-Aviv, Israel
February 24, 2021

Consolidated Statements of Financial Position

	Note	As of December 31, 2020	2019
		U.S. Dollars in thousands	
Assets			
Current Assets			
Cash and cash equivalents	5	$ 70,197	$ 42,662
Short-term investments	6	39,069	31,245
Trade receivables, net	7	22,108	23,210
Other accounts receivables	8	4,524	3,272
Inventories	9	42,016	43,173
Total Current Assets		177,914	143,562
Non-Current Assets			
Property, plant and equipment, net	10	25,679	24,550
Right-of-use assets	14b	3,440	4,022
Other long term assets	11	1,573	352
Contract asset	17e	2,059	-
Deferred taxes	21	-	1,311
Total Non-Current Assets		32,751	30,235
Total Assets		$ 210,665	$ 173,797
Liabilities			
Current Liabilities			
Current maturities of bank loans	14a	$ 238	$ 489
Current maturities of lease liabilities	14b	1,072	1,020
Trade payables	12	16,110	24,830
Other accounts payables	13	7,547	5,811
Deferred revenues	17	-	589
Total Current Liabilities		24,967	32,739
Non-Current Liabilities			
Bank loans	14a	36	257
Lease liabilities	14b	3,593	3,981
Deferred revenues	17e	2,025	232
Employee benefit liabilities, net	16	1,406	1,269
Total Non-Current Liabilities		7,060	5,739
Shareholder's Equity	19		
Ordinary shares		11,706	10,425
Additional paid in capital net		209,760	180,819
Capital reserve due to translation to presentation currency		(3,490)	(3,490)
Capital reserve from hedges		357	8
Capital reserve from financial assets measured at fair value through other comprehensive income		-	145
Capital reserve from share-based payments		4,558	8,844
Capital reserve from employee benefits		(320)	(359)
Accumulated deficit		(43,933)	(61,073)
Total Shareholder's Equity		178,638	135,319
Total Liabilities and Shareholder's Equity		$ 210,665	$ 173,797

The accompanying notes are an integral part of the Consolidated Financial Statements.

Consolidated Statements of Profit or Loss and Other Comprehensive Income

	Note	For the Year Ended December 31, 2020	2019	2018
		U.S. Dollars in thousands, except for share and per share data		
Revenues from proprietary products	1a	$ 100,916	$ 97,696	$ 90,784
Revenues from distribution		32,330	29,491	23,685
Total revenues	22a,b	133,246	127,187	114,469
Cost of revenues from proprietary products		57,750	52,425	52,796
Cost of revenues from distribution		27,944	25,025	20,201
Total cost of revenues	22c	85,694	77,450	72,997
Gross profit		47,552	49,737	41,472
Research and development expenses	22d	13,609	13,059	9,747
Selling and marketing expenses	22e	4,518	4,370	3,630
General and administrative expenses	22f	10,139	9,194	8,525
Other expense		49	330	311
Operating income		19,237	22,784	19,259
Financial income	22g	1,027	1,146	830
Income (expenses) in respect of securities measured at fair value, net	22g	102	(5)	(178)
Income (expenses) in respect of currency exchange differences and derivatives instruments, net	22g	(1,535)	(651)	602
Financial expense	22g	(266)	(293)	(172)
Income before tax on income		18,565	22,981	20,341
Taxes on income	21	1,425	730	(1,955)
Net Income		$ 17,140	22,251	$ 22,296
Other Comprehensive Income:				
Amounts that will be or that have been reclassified to profit or loss when specific conditions are met				
Gain (loss) from securities measured at fair value through other comprehensive income		(188)	143	51
Gain (loss) on cash flow hedges		876	92	(176)
Net amounts transferred to the statement of profit or loss for cash flow hedges		(528)	(23)	70
Items that will not be reclassified to profit or loss in subsequent periods:				
Remeasurement gain (loss) from defined benefit plan		64	(388)	340
Tax effect		19	(11)	(9)
Total comprehensive income		$ 17,383	$ 22,064	$ 22,572
Earnings per share attributable to equity holders of the Company:	23			
Basic net earnings per share		$ 0.39	$ 0.55	$ 0.55
Diluted net earnings per share		$ 0.38	$ 0.55	$ 0.55

The accompanying notes are an integral part of the Consolidated Financial Statements.

Consolidated Statements of Changes in Equity

	Share capital	Additional paid in capital	Capital reserve From securities measured at fair value through other Comprehensive income	Capital reserve due to translation to presentation currency	Capital reserve from hedges	Capital reserve from share based payments	Capital reserve from employee benefits	Accumulated deficit	Total equity
	U.S. Dollars in thousands								
Balance as of December 31, 2017	$ 10,400	$ 177,874	$ (4)	$ (3,490)	$ 46	$ 9,566	$ (337)	$ (104,563)	$ 89,492
Cumulative effect of Initial application of IFRS 15	-	-	-	-	-	-	-	(757)	(757)
Balance as at January 1, 2018 (after initially application of IFRS 15)	10,400	177,874	(4)	(3,490)	46	9,566	(337)	(105,320)	88,735
Net income	-	-	-	-	-	-	-	22,296	22,296
Other comprehensive income (loss)	-	-	50	-	(106)	-	340	-	284
Tax effect			(12)		3	-	1		(8)
Total comprehensive income (loss)	-	-	38	-	(103)	-	341	22,296	22,572
Exercise and forfeiture of share-based payment into shares	9	1,161	-	-	-	(1,161)	-	-	9
Cost of share base payment	-	-	-	-	-	948	-	-	948
Tax effect	-	112	-	-	-	-	-	-	112
Balance as of December 31, 2018	$ 10,409	$ 179,147	$ 34	$ (3,490)	$ (57)	$ 9,353	$ 4	$ (83,024)	$ 112,376
Cumulative effect of initially application of IFRS 16	-	-	-	-	-	-	-	(300)	(300)
Balance as at January 1, 2019 (after Initial application of IFRS 16)	10,409	179,147	34	(3,490)	(57)	9,353	4	(83,324)	112,076
Net income								22,251	22,251
Other comprehensive income (loss)	-	-	143	-	69	-	(388)	-	(176)
Tax effect	-	-	(32)	-	(4)	-	25	-	(11)
Total comprehensive income (loss)	-	-	111	-	65	-	(363)	22,251	22,064
Exercise and forfeiture of share-based payment into shares	16	1,672	-	-	-	(1,672)	-	-	16
Cost of share-based payment	-	-	-	-	-	1,163	-	-	1,163
Balance as of December 31, 2019	$ 10,425	$ 180,819	$ 145	$ (3,490)	$ 8	$ 8,844	$ (359)	$ (61,073)	$ 135,319
Net income								17,140	17,140
Other comprehensive income (loss)			(188)		348		64		224
Tax effect			43		1		(25)		19
Total comprehensive income (loss)			(145)		349		39	17,140	17,383
Issuance of share	1,217	23,678							24,895
Exercise and forfeiture of share-based payment into shares	64	5,263				(5,263)			64
Cost of share-based payment						977			977
Balance as of December 31, 2020	$ 11,706	$ 209,760	$ -	$ (3,490)	$ 357	$ 4,558	$ (320)	$ (43,933)	$ (178,638)

The accompanying notes are an integral part of the Consolidated Financial Statements

Consolidated Statements of Cash Flows

	Note	For the year ended December 31, 2020	2019	2018
		U.S. Dollars in thousands		
Cash Flows from Operating Activities				
Net income		$ 17,140	$ 22,251	$ 22,296
Adjustments to reconcile net income to net cash provided by operating activities:				
Adjustments to the profit or loss items:				
Depreciation and amortization	10	4,897	4,519	3,703
Financial expense (income), net		672	(197)	(1,082)
Cost of share-based payment	20	977	1,163	948
Taxes on income	21	1,425	730	(1,955)
(Gain) loss from sale of property and equipment		(7)	(2)	55
Change in employee benefit liabilities, net		201	94	(16)
		8,165	6,307	1,653
Changes in asset and liability items:				
Decrease in trade receivables, net		1,332	5,117	2,311
Decrease (increase) in other accounts receivables		115	(214)	(1,336)
Increase (decrease) in inventories		1,157	(13,857)	(8,246)
Increase (decrease) in deferred expenses		(3,085)	399	235
(Decrease) increase in trade payables		(9,560)	6,259	(1,116)
Increase (decrease) in other accounts payables		1,736	863	(658)
Increase (decrease) in deferred revenues		1,204	(283)	(5,256)
		(7,101)	(1,716)	(14,066)
Cash paid during the year for:				
Interest paid		(209)	(243)	(54)
Interest received		1,211	1,106	739
Taxes paid		(101)	(134)	(22)
		901	729	663
Net cash provided by operating activities		$ 19,105	$ 27,571	$ 10,546

The accompanying notes are an integral part of the Consolidated Financial Statements.

Consolidated Statements of Cash Flows

	Note	For the year ended December 31, 2020	2019	2018
		U.S. Dollars in thousands		
Cash Flows from Investing Activities				
Investment in short term investments, net		$ (7,646)	$ 1,727	$ (2,322)
Purchase of property and equipment and intangible assets	10	(5,488)	(2,300)	(2,884)
Proceeds from sale of property and equipment		7	9	30
Net cash used in investing activities		(13,127)	(564)	(5,176)
Cash Flows from Financing Activities				
Proceeds from exercise of share base payments		64	16	9
Proceeds from issuance of ordinary shares, net		24,895	-	-
Repayment of lease liabilities		(1,103)	(1,070)	(136)
Repayment of long-term loans		(492)	(476)	(460)
Net cash provided by (used in) financing activities		23,364	(1,530)	(587)
Exchange differences on balances of cash and cash equivalent		(1,807)	(908)	629
Increase in cash and cash equivalents		27,535	24,569	5,412
Cash and cash equivalents at the beginning of the year		42,662	18,093	12,681
Cash and cash equivalents at the end of the year		$ 70,197	$ 42,662	$ 18,093
Significant non-cash transactions				
Right-of-use asset recognized with corresponding lease liability	14b	539	5,035	-
Purchase of property and equipment		$ 722	$ 992	$ 720

The accompanying notes are an integral part of the Consolidated Financial Statements.

NOTE 1: - GENERAL

a. General description of the Company and its activity

Kamada Ltd. ("the Company") is a plasma-derived biopharmaceutical company focused on orphan indications, with an existing marketed product portfolio and a late-stage product pipeline. The Company uses its proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce Alpha-1 Antitrypsin (AAT) in a highly-purified, liquid form, as well as other plasma-derived immune globulins. The Company's flagship product is Glassia® ("Glassia"), the first liquid, ready-to-use, intravenous plasma-derived AAT product approved by the U.S. FDA. The Company markets Glassia in the U.S. through a strategic partnership with Takeda Pharmaceuticals Company Limited ("Takeda") and in other counties through local distributors. The Company's second leading product is KamRab®, a rabies immune globulin (Human) for post-exposure prophylaxis against rabies infection. KamRab is FDA approved and is being marketed in the U.S. under the brand name KedRab through a strategic partnership with Kedrion S.p.A ("Kedrion"). In addition to Glassia and KedRab, the Company has a product line of four other plasma-derived pharmaceutical products administered by injection or infusion, that are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America and Asia. The Company has late-stage products in development, including an inhaled formulation of AAT for the treatment of AAT deficiency. In addition, the Company's intravenous AAT is in development for other indications, such as GvHD and prevention of lung transplant rejection, and during 2020, the Company initiated the development of a plasma derived immunoglobulin (IgG) product as a potential treatment for coronavirus disease (COVID-19). The Company leverages its expertise and presence in the plasma-derived protein therapeutics market by distributing more than 20 complementary products in Israel that are manufactured by third parties.

Pursuant to the agreement with Takeda (as detailed on Note 17) the Company will continue to produce Glassia for Takeda through 2021. Takeda will complete the technology transfer of Glassia, and pending FDA approval, will initiate its own production of Glassia for the U.S. market in 2021. Accordingly, following the transition of manufacturing to Takeda, the Company will terminate the manufacturing and sale of Glassia to Takeda resulting in a significant reduction in revenues. Pursuant to the agreement, upon initiation of sales of Glassia manufactured by Takeda, Takeda will pay royalties to the Company at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040.

The Company's activity is divided into two operating segments:

Proprietary Products	Development, manufacturing, sales and distribution of plasma-derived protein therapeutics.
Distribution	Distribute imported drug products in Israel, which are manufactured by third parties.

b. The Company's securities are listed for trading on the Tel Aviv stock exchange and on the NASDAQ.

The Company has four wholly-owned subsidiaries – Kamada Inc, Kamada Plasma LLC (wholly owned by Kamada Inc), Kamada Ireland limited and Kamada Biopharma Limited which as of December 31, 2021 are not active. In addition the Company owns 74% of Kamada Assets Ltd ("Kamada Assets").

c. Effects of the COVID-19 Outbreak:

Following the global COVID-19 outbreak, there has been a decrease in economic activity worldwide, including Israel. The spread of the COVID-19 pandemic led, inter alia, to a disruption in the global supply chain, a decrease in global transportation, restrictions on travel and work that were announced by the State of Israel and other countries worldwide as well as a decrease in the value of financial assets and commodities across all markets in Israel and the world.

The Company's business activity and commercial operation were affected by these factors, and the Company has taken several actions to ensure its manufacturing plant remains operational with limited disruption to its business continuity. The Company increased its inventory levels of raw materials through its suppliers and service providers to appropriately manage any potential supply disruptions and secure continued manufacturing. In addition, the Company is actively engaging its freight carriers to ensure inbound and outbound international delivery routes remain operational and identify alternative routes, if needed. The Company expedited shipments of certain of its products to its customer to minimize any potential shortages.

NOTE 1: - GENERAL (CONT.)

The Company is complying with the State of Israel mandates and recommendations with respect to its work-force management and currently maintains the work-force levels required to support its ongoing commercial operations. The Company has taken several precautionary health and safety measures to safeguard its employees and continues to monitor and assess orders issued by the State of Israel and other applicable governments to ensure compliance with evolving COVID-19 guidelines.

While COVID-19 related disruption had various effect on the Company's business activities, commercial operation, revenues and operational expenses, as a results of the actions taken by the Company to date, its overall results of operations for the year ended December 31, 2020 were not materially affected however, a number of factors, including but not limited to, continued effect of the factors mentioned above as well as, continued demand for the Company's products, including GLASSIA and KEDRAB, in the U.S. market and its distributed products in Israel, financial conditions of the Company's customer, suppliers and services providers, the Company's ability to manage operating expenses, additional competition in the markets that the Company competes, regulatory delays, prevailing market conditions and the impact of general economic, industry or political conditions in the U.S., Israel or otherwise, may have an effect on the Company's future financial position and results of operations.

The financial impact of these factors cannot be reasonably estimated at this time due to substantial uncertainty but may materially affect our business, financial condition and results of operations. The Company assess the impact of the COVID-19 in a number of possible scenarios and concluded that there are no uncertainties that may cast significant doubt on its ability to continue as a going concern or affect significantly on the Company liquidity.

d. Definitions

In these Financial Statements –

The Company	-	Kamada Ltd.
The Group	-	The Company and its subsidiaries.
Subsidiary	-	A company which the Company has a control over (as defined in IFRS 10) and whose financial statements are consolidated with the Company's Financial Statements.
Related parties	-	As defined in International Accounting Standard ("IAS") 24.
USD/$	-	U.S. dollar.
NIS	-	New Israeli Shekel
EUR	-	Euro

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation of financial statements

1. These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standard Board.

2. Measurement basis:

The Company's consolidated Financial Statements are prepared on a cost basis, except for financial instruments (including derivatives) at fair value through profit or loss and other comprehensive income such as marketable securities financial assets.

The Company has elected to present profit or loss items using the "function of expense" method.

b. The Company's operating cycle is one year.

c. The consolidated financial statements comprise the financial statements of companies that are controlled by the Company (subsidiaries). Control is achieved when the Company is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. The consolidation of the financial statements commences on the date on which control is obtained and ends when such control ceases.

The financial statements of the Company and of the subsidiaries are prepared as of the same dates and periods. The consolidated financial statements are prepared using uniform accounting policies by all companies in the Group. Significant intercompany balances and transactions, gains or losses resulting from intercompany transactions are eliminated in full in the consolidated financial statements.

d. Functional currency, presentation currency and foreign currency

1. Functional currency and presentation currency

The consolidated financial statements are presented in U.S. dollars, which is the Company's functional and presentation currency.

2. Transactions, assets and liabilities in foreign currency

Transactions denominated in foreign currency are recorded on initial recognition at the exchange rate at the date of the transaction. After initial recognition, monetary assets and liabilities denominated in foreign currency are translated at the end of each reporting period into the functional currency at the exchange rate at that date. Exchange differences are recognized in profit or loss. Non-monetary assets and liabilities measured at cost in a foreign currency are translated at the exchange rate at the date of the transaction. Non-monetary assets and liabilities denominated in foreign currency and measured at fair value are translated into the functional currency using the exchange rate prevailing at the date when the fair value was determined.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

e. Cash and cash equivalents

Cash comprise of cash at banks and on hand. Cash equivalents are considered as highly liquid investments, including unrestricted short-term bank deposits with an original maturity of three months or less from the date of purchase, which are subject to an insignificant risk of changes in value.

f. Short-term investments

Short-term investments comprised of bank deposits with a maturity of more than three months from the deposit date but less than one year and securities measured at fair value through other comprehensive income. The deposits are presented according to their terms of deposit.

g. Allowance for doubtful accounts

The allowance for doubtful accounts is determined in respect of specific debts whose collection, in the opinion of the Company's management, is doubtful. Impaired debts are derecognized when they are assessed as uncollectible. As of December 31, 2020 the Company has not recognized an allowance for doubtful accounts.

The Company did not recognize an allowance in respect of groups of customers that are collectively assessed for impairment since it did not identify any groups of customers which bear similar credit risks.

h. Inventories

Inventories are measured at the lower of cost and net realizable value. The cost of inventories comprises of the costs of purchase of raw and other materials and costs incurred in bringing the inventories to their present location and condition. Net realizable value is the estimated selling price in the ordinary course of business.

Cost of inventories is determined as follows:

Raw materials	At cost using the first-in, first-out method. Fair value of raw material received at no charge is not included in the inventory value.
Work in process	Costs of raw materials, direct and indirect costs including labor, other materials and other indirect manufacturing costs allocated to the in process manufactured batches through the end of the reporting period. The allocation of indirect costs is accounted for on a quarterly basis by dividing the total quarterly indirect manufacturing cost to the batches manufactured during that quarter based on predetermined allocation factors. The Company determines a standard manufacturing capacity for each quarter. To the extent the actual manufacturing capacity in a given quarter is lower than the predetermined standard, than a portion of the indirect costs which is equal to the product of the overall quarterly indirect costs multiplied by the quarterly manufacturing shortfall rate is recognized as costs of revenues
Finished products	Costs of raw materials, direct and indirect costs including labor, other materials and other indirect manufacturing costs allocated to the manufactured finished products through completion of manufacturing process.
Purchased products	At cost using the first-in, first-out method.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

The Company periodically evaluates the condition and age of inventories and accounts for impairment of inventories with a lower market value or which are slow moving.

i. Research and development costs

Research expenditures are recognized in profit or loss when incurred and include preclinical and clinical costs (as well as cost of materials associated with the development of new products or existing products for new therapeutic indications). In addition, these costs include additional product development activities with respect to approved and distributed products as well as post marketing commitment research and development activities.

An intangible asset arising from a development project or from the development phase of an internal project is recognized if the Company can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale; the Company's intention to complete the intangible asset and use or sell it; the Company's ability to use or sell the intangible asset; how the intangible asset will generate future economic benefits; the availability of adequate technical, financial and other resources to complete the intangible asset; and the Company's ability to measure reliably the expenditure attributable to the intangible asset during its development. Since the Company development projects are often subject to regulatory approval procedures and other uncertainties, the conditions for the capitalization of costs incurred before receipt of approvals are not normally satisfied and therefore, development expenditures are recognized in profit or loss when incurred.

j. Revenue recognition

On January 1, 2018, the Company initially adopted IFRS 15, "Revenue from Contracts with Customers" ("the IFRS 15 Standard"). The Company elected to apply the provisions of the IFRS 15 Standard using the modified retrospective method with the application of certain practical expedients and without restatement of comparative data. The accounting policy for revenue recognition applied from January 1, 2018, is as follows:

The Company recognizes revenue when the customer obtains control over the promised goods or services. Revenues are recognized at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer. The Company includes variable consideration, such as milestone payments or volume rebates, in the transaction price only when it is highly probable that its inclusion will not result in a significant revenue reversal in the future when the uncertainty has been subsequently resolved

In determining the amount of revenue from contracts with customers, the Company evaluates whether it is a principal or an agent in the arrangement. The Company is a principal when the Company controls the promised goods or services before transferring them to the customer. In these circumstances, the Company recognizes revenue for the gross amount of the consideration.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Identifying the contract

The Company account for a contract with a customer only when all of the following criteria are met:

a) The parties to the contract have approved the contract (in writing, orally or in accordance with other customary business practices) and are committed to perform their respective obligations;

b) The Company can identify each party's rights regarding the goods or services to be transferred;

c) The Company can identify the payment terms for the goods or services to be transferred;

d) The contract has commercial substance (i.e. the risk, timing or amount of the entity's future cash flows is expected to change as a result of the contract); and

e) It is probable that the Company will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer

For the purpose of paragraph (e) the Company examines, inter alia, the percentage of the advance payments received and the spread of the contractual payments, past experience with the customer and the status and existence of sufficient collateral.

If a contract with a customer does not meet all of the above criteria, consideration received from the customer is recognized as a liability until the criteria are met or when one of the following events occurs: the Company has no remaining obligations to transfer goods or services to the customer and any consideration promised by the customer has been received and cannot be returned; or the contract has been terminated and the consideration received from the customer cannot be refunded.

Combination of contracts

The Company accounts for multiple contracts as a single contract when all the contracts are signed at or near the same time with the same customer or with related parties of the customer, and when one of the following criteria is met:

a) The contracts are negotiated as a package with a single commercial objective.

b) The amount of consideration to be paid in one contract depends on the consideration of another contract.

c) The goods or services that the Company will provide according to the contracts represent a single performance obligation for the Company.

Identifying performance obligations

On the contract's inception date the Company assesses the goods or services promised in the contract with the customer and identifies the performance obligations in it.

The Company identifies the performance obligations when the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the Company promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. In order to examine whether a promise to transfer goods or services is separately identifiable, the Company examines whether it is providing a significant service of integrating the goods or services with other goods or services promised in the contract into one integrated outcome that is the purpose of the contract.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Option to purchase additional goods or services

An option that grants the customer the right to purchase additional goods or services constitutes a separate performance obligation in the contract only if the option grants to the customer a material right it would not have received without the original contract.

Determining the transaction price

The transaction price is the amount of the consideration that is expected to be received based on the contract terms. The Company takes into account the effects of all the following elements when determining the transaction price:

a) Variable consideration – The Company determines the transaction price separately for each contract with a customer. When exercising this judgment, the Company evaluates the effect of each variable amount in the contract, taking into consideration discounts, penalties, variations, claims, and non-cash consideration. The Company includes the estimated variable consideration in the transaction price only to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is resolved. The Company updates the estimated transaction price to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period.

b) Existence of a significant financing component – the Company adjusts the amount of the promised consideration in respect of the effects of the time value of money when certain advance payments provide the Company with a significant financing benefit. The financing component is recognized as interest expenses over the period, which are calculated according to the effective interest method.

c) Non-cash consideration - Non-cash consideration is measured at the fair value for goods receivable on a contract's inception.

d) Consideration payable to customers- The Company accounts for payments made to a customer as a reduction of the revenues from the customer when the Company recognizes revenue from the transfer of goods or services to the customer or the Company pays the consideration or promises to pay the consideration in accordance with the Company's customary business practices. When the consideration payable to a customer is a payment for a distinct good or service from the customer, then the Company accounts for the purchase of the good or service in the same way it accounts for other purchases from suppliers.

Allocating the transaction price

For contracts that consist of more than one performance obligation, at contract inception the Company allocates the contract transaction price to each performance obligation identified in the contract on a relative stand-alone selling price basis. The stand-alone selling price is the price at which the Company would sell the promised goods or services separately to a customer. When the stand-alone selling price is not directly observable by reference to similar transactions with similar customers, the Company applies suitable methods for estimating the stand-alone selling price including: the adjusted market assessment approach, the expected cost plus a margin approach and the residual approach. The Company may also use a combination of these approaches to allocate the transaction price in the contract.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Satisfaction of performance obligations

The Company recognizes revenue from contracts with customers when the control over the goods or services is transferred to the customer.

For most contracts, revenue recognition occurs at a point in time when control of the asset is transferred to the customer, generally on delivery of the goods. For agreements with a strategic partner, performance obligations are generally satisfied over time, given that the customer both simultaneously receives and consumes the benefits provided by the Company, or receives assets with no alternative use, for which the Company has an enforceable right to payment for performance completed to date. The method for measuring the progress of performance obligations that are satisfied over time usually based upon the deliverables forming part of performance obligations.

Contract modifications

A contract modification is a change in the scope or price (or both) of a contract that was approved by the parties to the contract. A contract modification can be approved in writing, orally or be implied by customary business practices. A contract modification can take place also when the parties to the contract have a disagreement regarding the scope or price (or both) of the modification or when the parties have approved the modification in scope of the contract but have not yet agreed on the corresponding price modification.

When a contract modification has not yet been approved by the parties, the Company continues to recognize revenues according to the existing contract, while disregarding the contract modification, until the date the contract modification is approved or the contract modification is legally enforceable.

The Company accounts for a contract modification as an adjustment of the existing contract since the remaining goods or services after the contract modification are not distinct and therefore constitute a part of one performance obligation that is partially satisfied on the date of the contract modification. The effect of the modification on the transaction price and on the rate of progress towards full satisfaction of the performance obligation is recognized as an adjustment to revenues (increase or decrease) on the date of the contract modification, meaning on a catch-up basis.

When a contract modification increases the scope of the contract as a result of adding distinct goods or services and the contract price changes by an amount reflecting the stand-alone selling prices of the additional goods or services, the Company accounts for the contract modification as a separate contract.

Costs to fulfill a contract:

Costs incurred in fulfilling contracts or anticipated contracts with customers are recognized as an asset when the costs generate or enhance the Company's resources that will be used in satisfying or continuing to satisfy the performance obligations in the future and are expected to be recovered. Costs to fulfill a contract comprise direct identifiable costs and indirect costs that can be directly attributed to a contract based on a reasonable allocation method. Costs to fulfill a contract are amortized on a systematic basis that is consistent with the provision of the services under the specific contract.

An impairment loss in respect of capitalized costs to fulfill a contract is recognized in profit or loss when the carrying amount of the asset exceeds the remaining amount of consideration that the Company expects to receive for the goods or services to which the asset relates less the costs that relate directly to providing those goods or services and that have not been recognized as expenses.

Principal or agent

When another party is involved in providing goods or services to the customer, the Company examines whether the nature of its promise is a performance obligation to provide the defined goods or services itself, which means the Company is a principal and therefore recognizes revenue in the gross amount of the consideration, or to arrange that another party provide the goods or services which means the Company is an agent and therefore recognizes revenue in the amount of the net commission.

The Company is a principal when it controls the promised goods or services before their transfer to the customer. Indicators that the Company controls the goods or services before their transfer to the customer include, inter alia, as follows: the Company is the primary obligor for fulfilling the promises in the contract; the Company has inventory risk before the goods or services are transferred to the customer; and the Company has discretion in setting the prices of the goods or services.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Analysis of major contracts:

As of December 31, 2020, 2019 and 2018 the Company generate revenue mainly from sale of products to strategic partners and distributors as well as from the licensing of our technology and distribution rights.

In the majority of contracts, revenue recognition occurs at a point in time when control of our product is transferred to the customer, generally on delivery of the goods.

With regards to certain contract with our strategic partner the Company analyzed the following:

The Company identified few performance obligations which include:

a. Grant of a license for distribution one of the Company's products in certain territories and the supply of predetermined minimum quantities.

b. The supply of a predetermined quantity of the Company's product for the purpose of clinical trials performed conducted by strategic partner.

c. Grant of a license for the use of the Company's knowledge and patents, and the provision of consulting services with respect to the transfer of technology.

The Company determines the transaction price and allocates the transaction price to the different performance obligation identified. For certain amounts of variable consideration the Company allocated to a certain performance obligation or to a distinct goods or services within it.

For each performance obligation identified, the Company recognizes revenue when (or as) it satisfies the performance obligation. The performance obligations are satisfied over time, as the customer both simultaneously receives and consumes the benefits provided by the Company, or receives assets with no alternative use, for which the Company has an enforceable right to payment for performance completed to date. The method for measuring the progress in performance obligations that are satisfied over time usually based upon the deliverables forming part of those performance obligations.

Deferred revenues

Deferred revenues include unearned amounts received from customers not yet recognized as revenues.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

k. Government grants:

Government grants are recognized when there is reasonable assurance that the grants will be received and the Company will comply with the attached conditions.

Government grants received from the Israel Innovation Authority (formerly: the Office of the Chief Scientist in Israel, "the IIA") are recognized upon receipt as a liability if future economic benefits are expected from the research project that will result in royalty-bearing sales.

A liability for the loan is first measured at fair value using a discount rate that reflects a market rate of interest. The difference between the amount of the grant received and the fair value of the liability is accounted for as a Government grant and recognized as a reduction of research and development expenses. After initial recognition, the liability is measured at amortized cost using the effective interest method. Royalty payments are treated as a reduction of the liability. If no economic benefits are expected from the research activity, the grant receipts are recognized as a reduction of the related research and development expenses. In that event, the royalty obligation is treated as a contingent liability in accordance with IAS 37.

l. Taxes on income

Taxes on income in profit or loss comprise of current taxes, deferred taxes and taxes in respect of prior years, which are recognized in profit or loss, except to the extent that the tax arises from items which are recognized directly in other comprehensive income or equity.

1. Current taxes:

The current tax liability is measured using the tax rates and tax laws that have been enacted or substantively enacted by the end of reporting period as well as adjustments required in connection with the tax liability in respect of previous years.

2. Deferred taxes:

Deferred taxes are computed in respect of carryforward losses and temporary differences between the carrying amounts in the financial statements and the amounts attributed for tax purposes.

Deferred taxes are measured at the tax rates that are expected to apply when the asset is realized or the liability is settled, based on tax laws that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax assets are reviewed at the end of each reporting period and reduced to the extent that it is not probable that they will be utilized. Deductible carryforward losses and temporary differences for which deferred tax assets had not been recognized are reviewed at the end of each reporting period and a respective deferred tax asset is recognized to the extent that their utilization is probable.

Deferred taxes are offset in the statement of financial position if there is a legally enforceable right to offset a current tax asset against a current tax liability and the deferred taxes relate to the same taxpayer and the same taxation authority.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

3. Uncertain tax positions

A provision for uncertain tax positions, including additional tax and interest expenses, is recognized when it is more probable than not that the Group will have to use its economic resources to pay the obligation..

As of December 31, 2020 and 2019, the application of IFRIC 23 did not have a material effect on the financial statements.

m. Leases

As of January 1, 2019 the Company initially applied IFRS 16, "Leases" ("the Standard").

The Company chose to apply the provisions of the Standard using the modified retrospective approach without restatement of comparative data.

The accounting policy for leases applied effective from January 1, 2019, is as follows:

The Company accounts for a contract as a lease when the contract terms convey the right to control the use of an identified asset for a period of time in exchange for consideration.

On the inception date of the lease, the Company determines whether the arrangement is a lease or contains a lease, while examining if it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. In its assessment of whether an arrangement conveys the right to control the use of an identified asset, the Company assesses whether it has the following two rights throughout the lease term:

a) The right to obtain substantially all the economic benefits from use of the identified asset; and

b) The right to direct the identified asset's use.

The Company as a lessee:

For leases in which the Company is the lessee, the Company recognizes on the commencement date of the lease a right-of-use asset and a lease liability, excluding leases whose term is up to 12 months and leases for which the underlying asset is of low value. For these excluded leases, the Company has elected to recognize the lease payments as an expense in profit or loss on a straight-line basis over the lease term. In measuring the lease liability, the Company has elected to apply the practical expedient in the Standard and does not separate the lease components from the non-lease components (such as management and maintenance services, etc.) included in a single contract.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

On the commencement date, the lease liability includes all unpaid lease payments discounted at the interest rate implicit in the lease, if that rate can be readily determined, or otherwise using the Company's incremental borrowing rate. After the commencement date, the Company measures the lease liability using the effective interest rate method.

On the commencement date, the right-of-use asset is recognized in an amount equal to the lease liability plus lease payments already made on or before the commencement date and initial direct costs incurred less any lease incentives received. The right-of-use asset is measured applying the cost model and depreciated over the shorter of its useful life or the lease term. The Company tests for impairment of the right-of-use asset whenever there are indications of impairment pursuant to the provisions of IAS 36.

Depreciation of right-of-use asset

After lease commencement, a right-of-use asset is measured on a cost basis less accumulated depreciation and accumulated impairment losses and is adjusted for re-measurements of the lease liability. Depreciation is calculated on a straight-line basis over the useful life or contractual lease period, whichever earlier, as follows:

	%	Mainly %
Land and Buildings	10	10
Vehicles	20-33	33
office equipment (i.e. printing and photocopying machines)	20	20

Lease extension and termination options:

A non-cancellable lease term includes both the periods covered by an option to extend the lease when it is reasonably certain that the extension option will be exercised and the periods covered by a lease termination option when it is reasonably certain that the termination option will not be exercised.

In the event of any change in the expected exercise of the lease extension option or in the expected non-exercise of the lease termination option, the Company re-measures the lease liability based on the revised lease term using a revised discount rate as of the date of the change in expectations. The total change is recognized in the carrying amount of the right-of-use asset until it is reduced to zero, and any further reductions are recognized in profit or loss.

Subleases:

In a transaction in which the Company is a lessee of an underlying asset (head lease) and the asset is subleased to a third party, the Company assesses whether the risks and rewards incidental to ownership of the right-of-use asset have been transferred to the sub-lessee, among others, by evaluating the sublease term with reference to the useful life of the right-of-use asset arising from the head lease.

When substantially all the risks and rewards incidental to ownership of the right-of-use asset have been transferred to the sub- lessee, the Company accounts for the sublease as a finance lease, otherwise it is accounted for as an operating lease. If the sublease is classified as a finance lease, the leased asset is derecognized on the commencement date and a new asset, "finance lease receivable" is recognized at an amount equivalent to the present value of the lease payments, discounted at the interest rate implicit in the lease. Any difference between the carrying amount of the leased asset before the derecognition and the carrying amount of the finance lease receivable is recognized in profit or loss.

Lease modification:

If a lease modification does not reduce the scope of the lease and does not result in a separate lease, the Company re-measures the lease liability based on the modified lease terms using a revised discount rate as of the modification date and records the change in the lease liability as an adjustment to the right-of-use asset.

If a lease modification reduces the scope of the lease, the Company recognizes a gain or loss arising from the partial or full reduction of the carrying amount of the right-of-use asset and the lease liability. The Company subsequently remeasures the carrying amount of the lease liability according to the revised lease terms, at the revised discount rate as of the modification date and records the change in the lease liability as an adjustment to the right-of-use asset.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

For additional information regarding right-of-use assets and lease liabilities and refer to Note 14.

The accounting policy for leases applied until December 31, 2018, is as follows:

The criteria for classifying leases as finance or operating leases depend on the substance of the agreements and are made at the inception of the lease in accordance with the following principles as set out in IAS 17.

The Company as lessee:

1. Finance lease

   Finance leases transfer to the Company substantially all the risks and benefits incidental to ownership of the leased asset. At the commencement of the lease term, the leased assets are measured at the fair value of the leased asset or, if lower, at the present value of the minimum lease payments.

   The leased asset is depreciated over the shorter of the lease term and the expected life of the leased asset.

2. Operating lease

   Lease agreements are classified as an operating lease if they do not transfer substantially all the risks and benefits incidental to ownership of the leased asset. Lease payments are recognized as an expense in profit or loss on a straight-line basis over the lease term.

n. Property, plant and equipment

Property, plant and equipment are measured at cost, including directly attributable costs, less accumulated depreciation and any related investment grants and excluding day-to-day servicing expenses. Cost includes spare parts and auxiliary equipment that can be used only in connection with the plant and equipment.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

The Company's assets include computer systems comprising hardware and software. Software forming an integral part of the hardware to the extent that the hardware cannot function without the software installed on it is classified as property, plant and equipment. In contrast, software that adds functionality to the hardware is classified as an intangible asset.

The cost of assets includes the cost of materials, direct labor costs, as well as any costs directly attributable to bringing the asset to the location and condition necessary for it to operate in the manner intended by management.

Depreciation is calculated on a straight-line basis over the useful life of the assets at annual rates as follows:

	%	Mainly %
Buildings	2.5-4	4
Machinery and equipment	10-20	15
Vehicles	15	15
Computers, software, equipment and office furniture	6-33	33
Leasehold improvements	(*)	10

(*) Leasehold improvements are depreciated on a straight-line basis over the shorter of the lease term (including the extension option held by the Company and intended to be exercised) and the expected life of the improvement.

The useful life, depreciation method and residual value of an asset are reviewed at the year-end and any changes are accounted for prospectively as a change in accounting estimate.

Depreciation of an asset ceases at the earlier of the date that the asset is classified as held for sale and the date that the asset is derecognized.

o Intangible assets

intangible assets, are in respect of distribution right, that are acquired by the Company, which have finite useful lives, are measured at cost less accumulated amortization and accumulated impairment losses. As regards intangible assets in respect of distribution right agreements, see also Note 11.

p Impairment of non-financial assets

The Company evaluates the need to record an impairment of the carrying amount of non-financial assets whenever events or changes in circumstances indicate that the carrying amount is not recoverable. If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount.

The recoverable amount is the higher of fair value less costs of sale and value in use. In measuring value in use, the expected future cash flows are discounted using a pre-tax discount rate that reflects the risks specific to the asset. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs.

An impairment loss of an asset, is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. Reversal of an impairment loss, as above, shall not be increased above the lower of the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years and its recoverable amount. The reversal of impairment loss of an asset presented at cost is recognized in profit or loss.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

q. Financial instruments

On January 1, 2018, the Company initially adopted IFRS 9, "Financial Instruments" ("the Standard"). The Company elected to apply the provisions of the Standard retrospectively without restatement of comparative data.

The accounting policy for financial instruments applied commencing from January 1, 2018, is as follows:

1. Financial assets

Financial assets are classified at initial recognition, and subsequently measured at amortized cost, fair value through other comprehensive income (OCI), and fair value through profit or loss. The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Company's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Company has applied the practical expedient, the Company initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs.

After initial recognition, the accounting treatment of financial assets is based on their classification as follows:

Debt financial instruments are subsequently measured at fair value through profit or loss (FVPL), amortized cost, or fair value through other comprehensive income (FVOCI). The classification is based on two criteria: the Company's business model for managing the assets; and whether the instruments' contractual cash flows represent 'solely payments of principal and interest' on the principal amount outstanding (the 'SPPI criterion').

The classification and measurement of the Company's debt financial assets are as follows:

a) Debt instruments at amortized cost for financial assets that are held within a business model with the objective to hold the financial assets in order to collect contractual cash flows that meet the SPPI criterion. This category includes the Company's Trade and other receivables.

b) Debt instruments at FVOCI, with gains or losses recycled to profit or loss on derecognition. Financial assets in this category are the Company's quoted debt instruments that meet the SPPI criterion and are held within a business model both to collect cash flows and to sell. Interest earned whilst holding Available For Sale (AFS) financial investments is reported as interest income using the effective interest rate method.

Financial assets at FVPL comprise derivative instruments unless they are designated as effective hedging instruments.

Impairment of financial assets

The Company evaluates at the end of each reporting period the loss allowance for financial debt instruments which are not measured at fair value through profit or loss. The Company distinguishes between two types of loss allowances:

a) Debt instruments whose credit risk has not increased significantly since initial recognition, or whose credit risk is low - the loss allowance recognized in respect of this debt instrument is measured at an amount equal to the expected credit losses within 12 months from the reporting date (12-month ECLs); or

b) Debt instruments whose credit risk has increased significantly since initial recognition, and whose credit risk is not low - the loss allowance recognized is measured at an amount equal to the expected credit losses over the instrument's remaining term (lifetime ECLs).

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

The Company has short-term financial assets such as trade receivables in respect of which the Company applies a simplified approach and measures the loss allowance in an amount equal to the lifetime expected credit losses.

An impairment loss on debt instruments measured at amortized cost is recognized in profit or loss with a corresponding loss allowance that is offset from the carrying amount of the financial asset, whereas the impairment loss on debt instruments measured at fair value through other comprehensive income is recognized in profit or loss with a corresponding loss allowance that is recorded in other comprehensive income and not as a reduction of the carrying amount of the financial asset in the statement of financial position.

The Company applies the low credit risk simplification in the Standard, according to which the Company assumes the debt instrument's credit risk has not increased significantly since initial recognition if on the reporting date it is determined that the instrument has a low credit risk, for example when the instrument has an external rating of "investment grade".

In addition, the Company considers that when contractual payments in respect of a debt instrument are more than 30 days past due, there has been a significant increase in credit risk, unless there is reasonable and supportable information that demonstrates that the credit risk has not increased significantly.

The Company considers a financial asset in default when contractual payments are more than 90 days past due. However, in certain cases, the Company considers a financial asset to be in default when external or internal information indicates that the Company is unlikely to receive the outstanding contractual amounts in full.

The Company considers a financial asset that is not measured at fair value through profit or loss as credit-impaired when one or more events that have a detrimental impact on the estimated future cash flows of that financial asset have occurred. The Company takes into consideration the following events as evidence that a financial asset is credit impaired:

a) significant financial difficulty of the issuer or borrower;

b) a breach of contract, such as a default or past due event;

c) a concession granted to the borrower due to the borrower's financial difficulties that would otherwise not be granted;

d) it is probable that the borrower will enter bankruptcy or financial reorganization;

e) the disappearance of an active market for that financial asset because of financial difficulties; or

f) the purchase or origination of a financial asset at a deep discount that reflects the incurred credit losses.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Company expects to receive. For other debt financial assets (i.e., debt securities at FVOCI), the ECL is based on the 12-month ECL. The 12-month ECL is the portion of lifetime ECLs that results from default events on a financial instrument that are possible within 12 months after the reporting date. As of December 31, 2020 there is no ECL allowance.

2. Financial liabilities

Financial liabilities within the scope of IFRS 9 are initially measured at fair value less transaction costs that are directly attributable to the issue of the financial liability.

After initial recognition, the accounting treatment of financial liabilities is based on their classification as follows:

a) Financial liabilities measured at amortized cost

Loans, including leases, are measured based on their terms at amortized cost using the effective interest method taking into account directly attributable transaction costs.

b) Financial liabilities measured at fair value

Derivatives are classified as fair value through profit and loss unless they are designated as effective hedging instruments. Transaction costs are recognized in profit or loss.

After initial recognition, changes in fair value are recognized either in profit or loss for non-hedge accounting derivatives or in other comprehensive income for hedge accounting derivatives.

r. Fair value measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

Fair value measurement is based on the assumption that the transaction will take place in the asset's or the liability's principal market, or in the absence of a principal market, in the most advantageous market.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

Fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Company uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 - quoted prices (unadjusted) in active markets for identical assets or liabilities.

- Level 2 - inputs other than quoted prices included within Level 1 that are observable either directly or indirectly.

- Level 3 - inputs that are not based on observable market data (valuation techniques which use inputs that are not based on observable market data).

1. Offsetting financial instruments

Financial assets and financial liabilities are offset and the net amount is presented in the statement of financial position if there is a legally enforceable right to set off the recognized amounts and there is an intention either to settle on a net basis or to realize the asset and settle the liability simultaneously.

The right of set-off must be legally enforceable not only during the ordinary course of business of the parties to the contract but also in the event of bankruptcy or insolvency of one of the parties. In order for the right of set-off to be currently available, it must not be contingent on a future event, there may not be periods during which the right is not available, or there may not be any events that will cause the right to expire.

2. De-recognition of financial instruments

a. Financial assets

Financial assets are derecognized when the contractual rights to the cash flows from the financial asset expire or the Company has transferred its contractual rights to receive cash flows from the financial asset or assumes an obligation to pay the cash flows in full without material delay to a third party and has transferred substantially all the risks and rewards of the asset, or has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

b. Financial liabilities

A financial liability is derecognized when it is extinguished, that is when the obligation is discharged or cancelled or expires. A financial liability is extinguished when the debtor (the Company) discharges the liability by paying in cash, other financial assets, goods or services or is legally released from the liability.

s. Derivative financial instruments designated as hedges

The Company enters into contracts for derivative financial instruments such as forward currency contracts and cylinder strategy in respect of foreign currency to hedge risks associated with foreign exchange rates fluctuations and cash flows risk. Such derivative financial instruments are carried as financial assets when the fair value is positive and as financial liabilities when the fair value is negative.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

At the inception of a hedge relationship, the Company formally designates and documents the hedge relationship to which the Company wishes to apply hedge accounting and the risk management objective and strategy for undertaking the hedge. The hedge effectiveness is assessed at the end of each reporting period.

Any gains or losses arising from changes in the fair value of derivatives that do not qualify for hedge accounting are recorded immediately in profit or loss.

Cash flow hedges

The effective portion of the gain or loss on the hedging instrument is recognized as other comprehensive income (loss), while any ineffective portion is recognized immediately in profit or loss.

Amounts recognized as other comprehensive income (loss) are reclassified to profit or loss when the hedged transaction affects profit or loss, such as when the hedged income or expense is recognized or when a forecast payment occurs.

If the forecast transaction or firm commitment is no longer expected to occur, amounts previously recognized in other comprehensive income are reclassified to profit or loss. If the hedging instrument expires or is sold, terminated or exercised, or if its designation as a hedge is revoked, amounts previously recognized in other comprehensive income remain in other comprehensive income until the forecast transaction or firm commitment occurs.

t. Provisions

A provision in accordance with IAS 37 is recognized when the Company has a present (legal or constructive) obligation as a result of a past event, it is expected to require the use of economic resources to clear the obligation and a reliable estimate can be made of it. The expense is recognized in the statement of profit or loss net of any reimbursement.

u. Employee benefit liabilities

The Company has several employee benefit plans:

1. Short-term employee benefits

Short-term employee benefits include salaries, paid annual leave, paid sick leave, recreation and social security contributions and are recognized as expenses as the services are rendered. A liability in respect of a cash bonus is recognized when the Company has a legal or constructive obligation to make such payment as a result of past service rendered by an employee and a reliable estimate of the amount can be made.

2. Post-employment benefits

The post-employment benefits plans are normally financed by contributions to insurance companies and classified as defined contribution plans or as defined benefit plans.

The Company has defined contribution plans pursuant to Section 14 to the Israeli Severance Pay Law under which the Company pays fixed contributions to certain employees under Section 14 and will have no legal or constructive obligation to pay further contributions.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Contributions to the defined contribution plan in respect of severance or retirement pay are recognized as an expense when contributed concurrently with performance of the employee's services.

In addition the Company operates a defined benefit plan in respect of severance pay pursuant to the Israeli Severance Pay Law. According to the Law, employees are entitled to severance pay upon dismissal or retirement. The liability for termination of employment is measured using the projected unit credit method. The actuarial assumptions include expected salary increases and rates of employee's turnover based on the estimated timing of payment. The amounts are presented based on discounted expected future cash flows using a discount rate determined by reference to market yields at the reporting date on high quality corporate bonds that are linked to the Consumer Price Index with a term that is consistent with the estimated term of the severance pay obligation.

In respect of its severance pay obligation to certain of its employees, the Company makes current deposits in pension funds and insurance companies ("the plan assets"). Plan assets comprise assets held by a long-term employee benefit fund or qualifying insurance policies. Plan assets are not available to the Company's own creditors and cannot be returned directly to the Company.

The liability for employee benefits shown in the statement of financial position reflects the present value of the defined benefit obligation less the fair value of the plan assets.

Re-measurements of the net liability are recognized in other comprehensive income in the period in which they occur.

v. Share-based payment transactions

The Company's employees and Board of Directors members are entitled to remuneration in the form of equity-settled share- based payment transactions.

Equity-settled transactions

The cost of equity-settled transactions (options and restricted shares) with employees and Board of Directors members is measured at the fair value of the equity instruments granted at grant date. The fair value of options is determined using a standard option pricing model. The fair value of restricted shares is determined using the share price at the grant date.

The cost of equity-settled transactions is recognized in profit or loss together with a corresponding increase in shareholder's equity during the period which the performance and/or service conditions are to be satisfied ending on the date on which the relevant employees become entitled to the award ("the vesting period"). The cumulative expense recognized for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Company's best estimate of the number of equity instruments that will ultimately vest.

No expense is recognized for awards that do not ultimately vest.

In the event that the Company modifies the conditions on which equity-instruments were granted, an additional expense is calculated and recognized over the remaining vesting period for any modification that increases the total fair value of the share-based payment arrangement or is otherwise beneficial to the employee or director at the modification date.

w. Earnings (loss) per Share

Earnings (loss) per share are calculated by dividing the net income (loss) attributable to Company shareholders by the weighted number of ordinary shares outstanding during the period. Ordinary shares underlying shares options or restricted shares are only included in the calculation of diluted income (loss) per share when their impact dilutes the income (loss) per share. Furthermore, potential ordinary shares converted during the period are included under diluted income (loss) per share only until the conversion date, and from that date on are included under basic income (loss) per share.

x. Reclassification of prior years' amounts

Certain amounts in prior years' financial statements have been reclassified to conform to the current year's presentation. The reclassification had no effect on previously reported net loss or shareholders' equity.

NOTE 3: - SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS

In the process of applying the significant accounting policies, the Group has made the following judgments which have the most significant effect on the amounts recognized in the financial statements:

a. Judgments

- Determining the fair value of share-based payment transactions

  The fair value of share-based payment transactions is determined upon initial recognition by an acceptable option pricing model. The inputs to the model include share price, exercise price and assumptions regarding expected volatility, expected life of share option and expected dividend yield.

- Discount rate for a lease liability

  When the Company is unable to readily determine the discount rate implicit in a lease in order to measure the lease liability, the Company uses an incremental borrowing rate. That rate represents the rate of interest that the Company would have to pay to borrow over a similar term and with similar security, the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment. When there are no financing transactions that can serve as a basis, the Company determines the incremental borrowing rate based on its credit risk, the lease term and other economic variables deriving from the lease contract's conditions and restrictions. In certain situations, the Company is assisted by an external valuation expert in determining the incremental borrowing rate.

- Revenue

  Identification of performance obligations in contracts with customers:

  In order to identify distinct performance obligations in a contract with a customer, the Company uses judgment when it examines whether it is providing a significant service of integrating the goods or services in the contract into one integrated outcome.

  Measurement of variable consideration

  In order to determine the transaction price, the Company estimates the amount of the variable consideration and recognizes revenue in an amount where there is a high probability that its inclusion will not result in a significant revenue reversal in the future after the uncertainty has been resolved.

  Existence of a significant financing component:

  When assessing whether a contract includes a significant financing component, the Company examines, inter alia, the expected length of time between the date it transfers the promised goods or services to the customer and the date the customer pays for these goods or services, as well as the difference and the reasons for the difference, if any, between the promised consideration and the cash selling price of the promised goods or services.

NOTE 3: - SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS (CONT.)

Determining how performance obligations are fulfilled:

When determining that control over goods or services is transferred to the customer over time and that therefore revenue should be recognized over time, the Company relies on legal opinions, provisions of the contract and relevant provisions of the law indicating that the Company has a right to enforce fulfillment of the contract.

The Company assesses the criteria for recognition of revenue related to up-front payments and milestones as outlined by IFRS 15. Judgment is necessary to determine over which period the Company will satisfy its performance obligations related to up-front payments and milestones and whether financing component exists. For additional information, refer to Note 17a.

- Inventory

Work in process and Finished Good including direct and indirect costs. The allocation of indirect costs is accounted for on a quarterly basis by dividing the total quarterly indirect manufacturing cost to the batches manufactured during that quarter based on predetermined allocation factors. The criteria for allocation of indirect manufacturing expense to manufactured batches which eventually effect our inventory value is subject to Company judgment.

b. Estimates and assumptions

The preparation of the financial statements requires management to make estimates and assumptions that have an effect on the application of the accounting policies and on the reported amounts of assets, liabilities, revenues and expenses. Changes in accounting estimates are reported in the period of the change in estimate.

The key assumptions made in the financial statements concerning uncertainties at the end of the reporting period and the critical estimates computed by the Company that may result in a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

- Pensions and other post-employment benefits

The liability in respect of post-employment defined benefit plans is determined using actuarial valuations. The actuarial valuation involves making assumptions about, among others, discount rates, expected rates of return on assets, future salary increases and mortality rates. Due to the long-term nature of these plans, such estimates are subject to significant uncertainty.

NOTE 3: - SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS (CONT.)

- Lease extension and/or termination options

  In evaluating whether it is reasonably certain that the Company will exercise an option to extend a lease or not exercise an option to terminate a lease, the Company considers all relevant facts and circumstances that create an economic incentive for the Company to exercise the option to extend or not exercise the option to terminate such as: significant amounts invested in leasehold improvements, the significance of the underlying asset to the Company's operation and whether it is a specialized asset, the Company's past experience with similar leases, etc.

  After the commencement date, the Company reassesses the term of the lease upon the occurrence of a significant event or a significant change in circumstances that affects whether the Company is reasonably certain to exercise an option or not exercise an option previously included in the determination of the lease term, such as significant leasehold improvements that had not been anticipated on the lease commencement date, sublease of the underlying asset for a period that exceeds the end of the previously determined lease period, etc.

- Provisions for clinical trial and related expenses

  Accrued expenses costs for clinical trial activities performed by third parties, are based on estimates on the progress of completion of the clinical trials or services, as of the end of each reporting period, pursuant to the contract with the third parties, and the agreed upon fee to be paid for such services.

- Inventory designated for R&D activities

  The Company recognizes inventory produced for commercial sale, including costs incurred prior to regulatory approval but subsequent to the filing of a regulatory request when the Company has determined that the inventory has probable future economic benefit. Inventory is not recognized prior to completion of a phase III clinical trial. For products with an approved indication, raw materials and purchased drug product associated with development programs are included in inventory and charged to research and development expense when consumed. For products without an approved indication, drug product is charged to research and development expense.

- Impairment of inventories with realizable value lower than cost or which are slow moving

  Inventories are measured at the lower of cost and net realizable value. The cost of inventories comprises costs of purchase of raw and other materials and costs incurred in bringing the inventories to their present location and condition. Net realizable value is the estimated selling price in the ordinary course of business, net of selling expenses. The estimation of realizable value can effect on the inventory value at the period end.

  In addition, and as part of the quarterly inventory valuation process, the Company assesses the potential effect on inventory in cases of deviations from quality standards in the manufacturing process to identify potential required inventory write offs. Such assessment is subject to Company's judgment.

- Recognition of deferred tax asset in respect of carry forward tax losses

  Deferred tax assets are recognized for unused carryforward tax losses and deductible temporary differences to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgment is required to determine the amount of deferred tax assets that can be recognized, based upon the timing and level of future taxable profits, its source and the tax planning strategy. For information regarding deferred taxes recognition, please refer to note 21.

- Impairment test for the production facility

  The Company performed an impairment test of its production facility. The Company calculated the recoverable amount of the production facility to determine whether the book value exceeds its recoverable amount. The impairment test was based on a Discount Cash Flow ("DCF") model using the Company's long term forecast. As of December 31, 2020 no impairment was recorded as the recoverable amount exceeded the book value.

NOTE 3: - SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS (CONT.)

- Legal claims

  In estimating the likelihood of outcome of legal claims filed against the Company, the Company relies on the opinion of its legal counsel. These estimates are based on the legal counsel's best professional judgment, taking into account the stage of proceedings and historical legal precedents in respect of the different issues. Since the outcome of the claims will be determined in courts, the results could differ from these estimates.

NOTE 4: - DISCLUSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION

a. Amendments to IFRS 9, IFRS 7, IFRS 16, IFRS 4 and IAS 39 regarding the IBOR reform:

In August 2020, the IASB issued amendments to IFRS 9, "Financial Instruments", IFRS 7, "Financial Instruments: Disclosures", IAS 39, "Financial Instruments: Recognition and Measurement", IFRS 4, "Insurance Contracts", and IFRS 16, "Leases" ("the Amendments").

The Amendments provide practical expedients when accounting for the effects of the replacement of benchmark InterBank Offered Rates (IBORs) by alternative Risk Free Interest Rates (RFRs).

Pursuant to one of the practical expedients, an entity will treat contractual changes or changes to cash flows that are directly required by the reform as changes to a floating interest rate. That is, an entity recognizes the changes in interest rates as an adjustment of the effective interest rate without adjusting the carrying amount of the financial instrument. The use of this practical expedient is subject to the condition that the transition from IBOR to RFR takes place on an economically equivalent basis.

In addition, the Amendments permit changes required by the IBOR reform to be made to hedge designations and hedge documentation without the hedging relationship being discontinued, provided certain conditions are met. The Amendments also provide temporary relief from having to meet the "separately identifiable" requirement according to which a risk component must also be separately identifiable to be eligible for hedge accounting.

The Amendments include new disclosure requirements in connection with the expected effect of the reform on an entity's financial statements, such as how the entity is managing the process to transition to the interest rate reform, the risks to which it is exposed due to the reform and quantitative information about IBOR-referenced financial instruments that are expected to change.

The Amendments are effective for annual periods beginning on or after January 1, 2021. The Amendments are to be applied retrospectively. However, restatement of comparative periods is not required. Early application is permitted.

The Company believes that the adoption of the Amendment will not have an effect on its financial statements.

b. Amendment to IAS 1, *Presentation of Financial Statements: Classification of Liabilities as Current or Non-Current*

In January 2020, the IASB issued an amendment to IAS 1, "Presentation of Financial Statements" ("the Amendment") regarding the criteria for determining the classification of liabilities as current or non-current. The Amendment replaces certain requirements for classifying liabilities as current or non-current. Thus for example, according to the Amendment, a liability will be classified as non-current when the entity has the right to defer settlement for at least 12 months after the reporting period, and it "has substance" and is in existence at the end of the reporting period, this instead of the requirement that there be an "unconditional" right. According to the Amendment, a right is in existence at the reporting date only if the entity complies with conditions for deferring settlement at that date. Furthermore, the Amendment clarifies that the conversion option of a liability will affect its classification as current or non-current, other than when the conversion option is recognized as equity.

The Amendment is effective for reporting periods beginning on or after January 1, 2023 with earlier application being permitted. The Amendment is applicable retrospectively, including an amendment to comparative data.

The Company has not yet commenced examining the effects of applying the Amendment on the financial statements.

NOTE 4: - DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (CONT.)

c. Amendment to IAS 37, *Provisions, Contingent Liabilities and Contingent Assets*

In May 2020, the IASB issued an amendment to IAS 37, regarding which costs a company should include when assessing whether a contract is onerous ("the Amendment"). According to the Amendment, when assessing whether a contract is onerous, the costs of fulfilling a contract that should be taken into consideration are costs that relate directly to the contract, which include as follows:

- Incremental costs; and

- An allocation of other costs that relate directly to fulfilling a contract (such as depreciation expenses for fixed assets used in fulfilling that contract and other contracts).

The Amendment is effective retrospectively for annual periods beginning on or after January 1, 2022, in respect of contracts where the entity has not yet fulfilled all its obligations. Early application is permitted. Upon application of the Amendment, the entity will not restate comparative data, but will adjust the opening balance of retained earnings at the date of initial application, by the amount of the cumulative effect of the Amendment.

The Company has not yet commenced examining the effects of the Amendment on the financial statements.

d. Amendment to IAS 16, *Property, Plant and Equipment*

In May 2020, the IASB issued an amendment to IAS 16, "Property, Plant and Equipment" ("the Amendment") The Amendment annuls the requirement by which in the calculation of costs directly attributable to fixed assets, the net proceeds from selling certain items that were produced while the Company tested the functioning of the asset should be deducted (such as samples that were produced when testing the equipment). Instead, such proceeds shall be recognized in profit or loss according to the relevant standards and the cost of the sold items will be measured according to the measurement requirements of IAS 2, *Inventories*.

The Amendment is effective for annual periods beginning on or after January 1, 2022. Early application is permitted. The Amendment shall be applied on a retrospective basis, including an amendment of comparative data, only with respect to fixed asset items that have been brought to the location and condition required for them to operate in the manner intended by management subsequent to the earliest reporting period presented at the date of initial application of the Amendment. The cumulative effect of the Amendment will adjust the opening balance of retained earnings for the earliest reporting period presented.

The Company has not yet commenced examining the effects of the Amendment on the financial statements.

NOTE 5: - CASH AND CASH EQUIVALENTS

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Cash and deposits for immediate withdrawal	$ 20,075	$ 25,559
Cash equivalents in USD deposits (1)	47,011	17,017
Cash equivalents in NIS deposits (2)	3,111	86
Total Cash and Cash Equivalents	$ 70,197	$ 42,662

(1) The deposits bear interest of 0.21%-0.52% per year, as of December 31, 2020.
(2) The deposits bear interest of 0.18% per year, as of December 31, 2020 and 0.02% per year, as of December 31, 2019.

NOTE 6: - SHORT-TERM INVESTMENTS

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Fair value through other comprehensive income	$ -	$ 12,832
Bank deposits in USD (1)	39,069	18,413
Total Short-Term Investments	$ 39,069	$ 31,245

(1) The deposits bear interest of 0.63%-0.89% and 2.5%-3.3% per year, as of December 31, 2020 and 2019, respectively.

NOTE 7: - TRADE RECEIVABLES, NET

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Open accounts:		
In NIS	$ 10,756	$ 8,357
In USD	11,219	14,920
	$ 21,975	$ 23,277
Checks receivable	133	-
	$ 22,108	$ 23,277
Less allowance for doubtful accounts(1)	-	(67)
Total Trade receivables, net	$ 22,108	$ 23,210

(1) Allowance for doubtful accounts:

December 31, 2019	(67)
Provision for the year	67
December 31, 2020	-

An analysis of past due but not impaired trade receivables with reference to reporting date:

		Past due trade receivables with aging of					
	Neither past due nor impaired	Up to 30 Days	31-60 Days	61-90 Days	91-120 Days	Over 121 days	Total
December 31, 2020	$ 20,389	$ 1,180	$ 7	$ 6	$ -	$ 526[1]	$ 22,108
December 31, 2019	$ 22,617	$ 469	$ 25	$ 33	$ 65	$ 68	$ 23,277

(1) The amount was collected during January,2021.

NOTE 8: - OTHER ACCOUNTS RECEIVABLES

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Prepaid expenses	$ 2,105	$ 1,240
Inventory designated for R&D activities	1,026	-
Government authorities	735	1,838
Derivatives financial instruments mainly measured at fair value through other comprehensive income	448	15
Accrued income	202	101
Accrued interest	-	70
Other	8	8
Total Other Accounts Receivables	$ 4,524	$ 3,272

NOTE 9: - INVENTORIES

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Finished products	$ 13,459	$ 12,016
Purchased products	6,751	10,412
Work in progress	8,389	9,043
Raw materials	13,417	11,702
Total Inventories	$ 42,016	$ 43,173

(1) During the years 2020, 2019 and 2018, the Company recognized, at cost of revenues, as impairment for inventories carried at net realizable value totaled of $1,482 thousands, $334 thousands and $61 thousands, respectively.

NOTE 10: - PROPERTY, PLANT AND EQUIPMENT

a. Composition and movement:

2020

	Land and Buildings (1)	Machinery and Equipment (1)	Vehicles	Computers, Software, Equipment and Office Furniture	Leasehold Improvements	Total
	U.S. Dollars in thousands					
Cost						
Balance at January 1, 2020	$ 32,714	$ 28,198	$ 85	$ 7,218	$ 1,139	$ 69,354
Additions	944	3,175	-	894	-	5,013
Sale and write-off	-	(74)	(54)		-	(128)
Balance as of December 31, 2020	33,658	31,299	31	8,112	1,139	74,239
Accumulated Depreciation						
Balance as of January 1, 2020	18,639	20,524	70	5,267	304	44,804
Depreciation	1,410	1,660	4	694	116	3,884
Sale and write-off	-	(74)	(54)	-	-	(128)
Balance as of December 31, 2020	20,049	22,110	20	5,961	420	48,560
Depreciated cost as of December 31, 2020	$ 13,609	$ 9,189	$ 11	$ 2,151	$ 719	$ 25,679

(1) Including labor costs charged in 2020 to the cost of facilities, machinery and equipment in the amount of $746 thousands.

NOTE 10: - PROPERTY, PLANT AND EQUIPMENT (CONT.)

2019

	Land and Buildings (1)	Machinery and Equipment (1)	Vehicles	Computers, Software, Equipment and Office Furniture	Leasehold Improvements	Total
	U.S. Dollars in thousands					
Cost						
Balance at January 1, 2019	$ 31,613	$ 27,044	$ 85	$ 6,910	$ 1,125	$ 66,776
Additions	1,101	1,302	-	699	14	3,116
Sale and write-off	-	(148)	-	(391)	-	(539)
Balance as of December 31, 2019	32,714	28,198	85	7,218	1,139	69,354
Accumulated Depreciation						
Balance as of January 1, 2019(*)	17,407	19,090	65	5,022	189	41,773
Depreciation and impairment	1,232	1,575	5	636	115	3,563
Sale and write-off	-	(141)	-	(391)	-	(532)
Balance as of December 31, 2019	18,639	20,524	70	5,267	304	44,804
Depreciated cost as of December 31, 2019	$ 14,075	$ 7,674	$ 15	1,951	$ 835	$ 24,550

(1) Including labor costs charged in 2019 to the cost of facilities, machinery and equipment in the amount of $493 thousands.

b. As for liens, refer to Note 18.

c. Leasing rights of land from the Israel land administration.

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Under finance lease	$ 980	$ 992

A Company's subsidiary capitalized leasing rights from the Israel Land Administration for an area of 16,880 m² in Beit Kama, Israel, on which the Company's manufacturing plant and other buildings are located. The sum attributed to capitalized rights is presented under property, plant and equipment and is depreciated over the leasing period, which includes the option period.

During 2010, the Company signed an agreement with the Israel Land Administration to consolidate its leasing rights and extend the lease period to 2058, including an extension option for additional 49 years thereafter.

NOTE 11: - OTHER LONG TERM ASSETS

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Distribution right (1)	1,492	298
Long term pre-paid expenses	81	54
Total Other Long Term Assets	$ 1,573	$ 352

(1) During 2019 and 2020 the Company entered into agreements for the distribution right of certain therapeutic products to be distributed in Israel, subject to Israeli Ministry of Health ("IL MOH") marketing approval. Pursuant to the agreements, the Company was required to make certain upfront and milestone payments. These payments are accounted for as long term assets through obtaining IL MOH marketing authorization and it will be amortized during the product's economic useful life. As of December 31, 2020 no amortization was recorded.

NOTE 12: - TRADE PAYABLES

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Open debts mainly in USD	$ 3,523	$ 7,847
Open debts in EUR	5,413	11,426
Open debts in NIS	7,174	5,557
Total Trade Payables	$ 16,110	$ 24,830

NOTE 13: - OTHER ACCOUNTS PAYABLES

a. Composition:

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Employees and payroll accruals	$ 7,031	$ 5,669
Government grants (b)	222	-
Accrued Expenses and Others	294	142
Total Other Accounts Payables	$ 7,547	$ 5,811

b. Government grants:

	December 31, 2020
	U.S. Dollars in thousands
Presented in the statement of financial position and Profit or Loss and Other Comprehensive Income:	
Current Assets	$ 184
Current liability	222
Royalties paid during the year	-
Expense (income) carried to profit or loss	(279)

NOTE 14: - LOANS AND LEASES

a. Bank loans

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Bank loans	274	746
Less current maturities of bank loans	238	489
Total Long term bank loans	$ 36	$ 257

Bank loans

The bank loans are payable over 60 equal monthly installments. The loans bear fixed interest rate in the range of 3.15% -3.55%. No new bank loans received in 2020. See Note 18 regarding pledge information related to the bank loans.

b. Leases

The Company applies IFRS 16, Leases, as from January 1, 2019. The Company has lease agreements with respect to the following items:

1. Office and storage spaces:

   The Company has engaged in lease agreements for office and storage spaces for total of 10 years which includes lease extension for three year that will expire in 2026.

2. Vehicles:

   The Company leases vehicles for the use of certain of its employees. The lease term is mainly for three-year periods from several different leasing companies.

3. Office equipment (i.e. printing and photocopying machines):

   The Company leases office equipment (i.e. printing and photocopying machines) for five year periods.

Right-of-use assets composition and Changes in leas liabilities

2020

	Right-of-use-assets				
	Rented Offices	Vehicles	Computers, Software, Equipment and Office Furniture	Total	Lease Liabilities[1]
	U.S Dollars in thousands				
As of January 1, 2020	$ 3,033	$ 963	$ 26	$ 4,022	$ 5,001
Additions to right -of -use assets		539		539	539
Write-off		(110)		(110)	(112)
Depreciation expense	(434)	(571)	(6)	(1,011)	
Exchange rate differences					343
Repayment of lease liabilities					(1,106)
As of December 31, 2020	$ 2,599	$ 821	$ 20	$ 3,440	$ 4,665

(1) The weighted average incremental borrowing rate used to discount future lease payments in the calculation of the lease liability was in the range of 1.96%-4.6% evaluated based on credit risk, terms of the leases and other economic variables.

NOTE 14: - LOANS AND LEASES (CONT.)

2019

	Right-of-use-assets				
	Rented Offices	Vehicles	Computers, Software, Equipment and Office Furniture	Total	Lease Liabilities[2]
	U.S Dollars in thousands				
As of January 1, 2019[1]	$ 3,466	$ 663	$ 32	$ 4,161	$ 4,855
Additions to right -of -use assets	-	874		874	870
Write-off	-	(57)		(57)	(60)
Depreciation expense	(433)	(517)	(6)	(956)	-
Exchange rate differences	-	-		-	406
Repayment of lease liabilities	-	-		-	(1,070)
As of December 31, 2019	$ 3,033	$ 963	$ 26	$ 4,022	$ 5,001

(1) Following the initial application of IFRS 16, on January 1, 2019, the Company recorded operating lease commitment classified as a lease liability at the amount of $4,717 thousands with respect to office and storage spaces, vehicles and certain office equipment (i.e. printing and photocopying machines) at the amount of $4,022, $663 and $32 thousands, respectively.

(2) The weighted average incremental borrowing rate used to discount future lease payments in the calculation of the lease liability was in the range of 3.06%-4.6% evaluated based on credit risk, terms of the leases and other economic variables.

Below is the Consolidated Statements of Profit or Loss and Other Comprehensive Income impact for the year ended December 31, 2020 and December 31, 2019

	Expense decrease (increase) For the year ended on December 31,	
	2020	2019
	U.S Dollars in thousands	
Operating lease expense	$ 1,272	$ 1,182
Depreciation of right of use assets	(1,011)	(956)
Operating income	261	226
Finance expense	(192)	(212)
Net Income (loss)	$ 69	$ 14

Maturity analysis of the Company's lease liabilities (including interest) :

December 31, 2020

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Lease liabilities (including interest)	$ 1,238	$ 1,002	$ 806	$ 1,436	748	$ 5,230

December 31, 2019

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Lease liabilities (including interest)	$ 1,198	$ 1,000	$ 797	$ 1,352	1,364	$ 5,711

NOTE 14: - LOANS AND LEASES (CONT.)

Lease extension

The Company has leases that include extension options. These options provide flexibility in managing the leased assets and align with the Company's business needs.

The Company exercises significant judgement in deciding whether it is reasonably certain that the extension options will be exercised.

Office and storage spaces leases have extension options for additional three years. The Company have reasonably certain that the extension option will be exercised in order to avoid a significant adverse impact to its operating activities.

NOTE 15: - FINANCIAL INSTRUMENTS

a. Classification of financial assets and liabilities

The financial assets liabilities in the balance sheet are classified by groups of financial instruments pursuant to IFRS 9:

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Financial assets		
Financial assets at fair value through profit or loss:		
Foreign exchange forward contracts	$ -	$ 2
Financial assets at fair value through other comprehensive income:		
Cash flow hedges	457	13
Marketable debt securities	-	12,832
Financial assets at cost:		
Cash and cash equivalent	70,197	42,662
Short term bank deposits	39,069	18,413
Total assets measured at fair value through other comprehensive income	$ 109,723	$ 73,920
Total financial assets	$ 109,723	$ 73,922
Financial liabilities		
Financial assets at fair value through profit or loss:		
Foreign exchange forward contracts	$ 9	$ -
Financial liabilities measured at amortized cost:		
Bank loans	274	746
Leases	4,665	5,001
Total Financial liabilities measured at amortized cost:	$ 4,939	$ 5,747
Total financial and lease liabilities	$ 4,948	$ 5,747

NOTE 15: - FINANCIAL INSTRUMENTS (CONT.)

b. Financial risk factors

The Company's activities expose it to various financial risks, such as market risk (foreign currency risk, interest rate risk and price risk), credit risk and liquidity risk. The Company's investment policy focuses on activities that will preserve the Company's capital. The Company utilized derivatives to hedge certain exposures to risk.

Risk management is the responsibility of the Company Chief Executive Officer (CEO) and Company Chief Financial Officer (CFO), in accordance with the policy approved by the Board of Directors. The Board of Directors provides principles for the overall risk management.

1. Market risks

a) Foreign exchange risk

The Company operates in an international environment and is exposed to foreign exchange risk resulting from the exposure to different currencies, mainly the NIS and EUR. Foreign exchange risks arise from recognized assets and liabilities denominated in a foreign currency other than the functional currency, such as trade and other accounts receivables, trade and other accounts payables, loans and capital leases.

As of December 31, 2020 and 2019, the Company has a position in financial derivatives intended to hedge changes in the exchange rate of the USD vs. the NIS and the EUR (see also Note 15f. below).

b) Price risk

As of December 31, 2020 the company divested all its investments in debt securities (corporate and government) consequently the Company do not expose to price risk. As of December 31, 2019, the Company has financial instruments, classified as financial assets measured at fair value through other comprehensive income for which the Company is exposed to risk of fluctuations in the security price that is determined by reference to the quoted market price.

2. Credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, short-term bank deposits, marketable securities, trade receivables and foreign currency derivative contracts.

a) Cash, cash equivalent and short term investments:

The Company holds cash, cash equivalents, short term deposits and other financial instruments at major financial institutions in Israel. In accordance with Company policy, evaluations of the relative strength of credit of the various financial institutions are made on an ongoing basis.

Short-term investments include short-term deposits with low risk for a period less than one year.

b) Trade receivables:

The Company regularly monitors the credit extended to its customers and their general financial condition, and, when necessary, requires collateral as security for the debt such as letters of creditor and down payments. In addition, the Company partially insures its overseas sales with foreign trade risk insurance. Refer to Note 7 for additional information.

NOTE 15: - FINANCIAL INSTRUMENTS (CONT.)

The Company keeps constant track of customer debt and the Financial Statements include an allowance for doubtful accounts that adequately reflects, in the Company's assessment, the loss embodied in the debts the collection of which is in doubt.

The Company's maximum exposure to credit risk for the components of the statement of financial position as of December 31, 2020 and 2019 is the carrying amount of trade receivables.

c) Foreign currency derivative contracts:

The Company is exposed to foreign currency exchange movements, primarily in USD vs. NIS and EUR. Consequently, it enters into various foreign currency exchange contracts with major financial institutions (see also Note 15f. below).

3. Liquidity risk

The table below summarizes the maturity profile of the Company's financial liabilities based on contractual undiscounted payments:

December 31, 2020

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Trade payables	$ 16,110					$ 16,110
Other accounts payables	7,547					7,547
bank loans (including interest)	244	37				281
Lease liabilities (including interest)	1,238	1,002	806	1,436	748	5,230
	$ 25,139	$ 1,039	$ 806	$ 1,436	$ 748	$ 29,168

NOTE 15: - FINANCIAL INSTRUMENTS (CONT.)

December 31, 2019

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Trade payables	$ 24,830	-	-	-	-	$ 24,830
Other accounts payables	5,811	-	-	-	-	5,811
bank loans (including interest)	506	227	34	-	-	767
Lease liabilities (including interest)	1,198	1,000	797	1,352	1,364	5,711
	$ 32,345	$ 1,227	$ 831	$ 1,352	$ 1,364	$ 37,119

Changes in liabilities arising from financing activities

	January 1, 2020	Payments	Foreign exchange movement	New loans and leases	Write off	December 31, 2020
	U.S. Dollars in thousands					
Bank loans	$ 746	(492)	20	-	-	$ 274
Leases	5,001	(1,103)	340	539	(112)	4,665
Total	$ 5,747	$ (1,595)	$ 360	$ 539	$ (112)	$ 4,939

c. Fair value

The following table demonstrates the carrying amount and fair value of the financial assets and liabilities presented in the financial statements not at fair value:

	Carrying Amount		Fair Value	
	December 31,		December 31,	
	2020	2019	2020	2019
	U.S. Dollars in thousands			
Financial liabilities				
Bank loans	274	746	278	754
Leases	4,665	5,001	4,935	5,583
Total Financial liabilities	$ 4,939	$ 5,747	$ 5,213	$ 6,337

The fair value of the bank loans and leases was based on standard pricing valuation model such as DCF which considers the present value of future cash flows discounted at the interest rate that reflects market conditions (Level 3).

The carrying amount of cash and cash equivalents, short term bank deposits, trade and other receivables, trade and other payables approximates their fair value, due to the short term maturities of the financial instruments.

NOTE 15: - FINANCIAL INSTRUMENTS (CONT.)

d. Classification of financial instruments by fair value hierarchy

Financial assets (liabilities) measured at fair value:

Financial assets (liabilities) measured at fair value:	**Level 1**	**Level 2**
	U.S. Dollars in thousands	
December 31, 2020		
Derivatives instruments	-	448
	$ -	$ 448

	Level 1	**Level 2**
	U.S. Dollars in thousands	
December 31, 2019		
Debt securities (corporate and government) measured fair value through other comprehensive income	$ 4,289	8,543
Derivatives instruments	-	15
	$ 4,289	$ 8,558

During 2020 and 2019 there was no transfer due to the fair value measurement of any financial instrument from Level 1 to Level 2, and furthermore, there were no transfers to or from Level 3 due to the fair value measurement of any financial instrument.

Sensitivity tests and principal work assumptions

The selected changes in the relevant risk variables were determined based on management's estimate as to reasonable possible changes in these risk variables.

The Company has performed sensitivity tests of principal market risk factors that are liable to affect its reported operating results or financial position. The sensitivity tests present the profit or loss in respect of each financial instrument for the relevant risk variable chosen for that instrument as of each reporting date. The test of risk factors was determined based on the materiality of the exposure of the operating results or financial condition of each risk with reference to the functional currency and assuming that all the other variables are constant.

NOTE 15: - FINANCIAL INSTRUMENTS (CONT.)

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Sensitivity test to changes in market price of listed Securities		
Gain (loss) from change:		
5% increase in market price	$ -	$ 642
5% decrease in market price	$ -	$ (642)
Sensitivity test to changes in foreign currency:		
Gain (loss) from change:		
5% increase in NIS	$ (203)	$ (24)
5% decrease in NIS	$ 203	$ 24
5% increase in Euro	$ (253)	$ (552)
5% decrease in Euro	$ 253	$ 552

e. Linkage terms of financial liabilities by groups of financial instruments pursuant to IFRS 9:

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
In NIS:		
Bank loans measured at amortized cost	$ 274	$ 746
Leases measured at amortized cost	4,665	4,973
	$ 4,939	$ 5,719
In USD:		
Leases measured at amortized cost	$ -	$ 28

f. Derivatives and hedging:

Derivatives instruments not designated as hedging

The Company has foreign currency forward contracts designed to protect it from exposure to fluctuations in exchange rates, mainly of NIS and EUR, in respect of its trade receivables, trade payables and inventory. Foreign currency forward contracts are not designated as cash flow hedges, fair value or net investment in a foreign operation. These derivatives are not considered as hedge accounting. As of December 31, 2020 the fair value of the derivative instruments not designated as hedging was financial liabilities of $9 thousands. The open transactions for those derivatives were in an amount of $5,617 thousands.

Cash flow hedges:

As of December 31, 2020, the Company held NIS/USD hedging contracts (cylinder contracts) designated as hedges of expected future salaries expenses and for expected future purchases from Israeli suppliers.

The main terms of these positions were set to match the terms of the hedged items. As of December 31, 2020 the fair value of the derivative instruments designated as hedge accounting was an asset of $457 thousands. The open transactions for those derivatives were in an amount of $310 thousands.

Cash flow hedges of the expected salaries and suppliers expenses in December 31, 2020 was estimated as effective and accordingly a net unrecognized income was recorded in other comprehensive income in the amount of $348 thousands net. The ineffective portion were allocated to finance expense.

NOTE 16: - EMPLOYEE BENEFIT LIABILITIES, NET

Employee benefits consist of short-term benefits and post-employment benefits.

Post-employment benefits:

According to the labor laws and Severance Pay Law in Israel, the Company is required to pay compensation to an employee upon dismissal or retirement or to make current contributions in defined contribution plans pursuant to Section 14 of the Severance Pay Law, as specified below. The Company's liability is accounted for as a post-employment benefit only for employees not under Section 14. The computation of the Company's employee benefit liability is made in accordance with a valid employment contract or a collective bargaining agreement based on the employee's salary and employment terms which establish the entitlement to receive the compensation.

The post-employment employee benefits are normally financed by contributions classified as defined benefit plans, as detailed below:

1. Defined contribution deposit:

   The Company's agreements with part of its employees are in accordance with section 14 of the Israeli Severance Pay Law. Contributions made by the Company in accordance with Section 14 release the Company from any future severance liabilities in respect of those employees. The expenses for the defined benefit deposit in 2020, 2019 and 2018 were $1,299 thousands, $1,102 thousands and $992 thousands, respectively.

2. Defined benefit plans:

   The Company accounts for the payment of compensation as a defined benefit plan for which an employee benefit liability is recognized and for which the Company deposits amounts in a long-term employee benefit fund and in qualifying insurance policies.

3. Expenses recognized in comprehensive income (loss):

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Current service cost	$ 264	$ 282	$ 292
Interest expenses, net	22	24	25
Current service cost (income) due to the transfer of real yield from the compensation component to the royalties' component in executive insurance policies before 2004	1	(1)	3
Total employee benefit expenses	287	305	320
Actual return on plan assets	$ 35	$ 158	$ 171

NOTE 16: - EMPLOYEE BENEFIT LIABILITIES, NET (CONT.)

The expenses are presented in the Statement of Comprehensive income (loss) as follows

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Cost of revenues	$ 195	$ 201	$ 175
Research and development	45	62	50
Selling and marketing	22	16	75
General and administrative	25	26	20
	$ 287	$ 305	$ 320

4. The plan liabilities, net:

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Defined benefit obligation	$ 5,606	$ 5,058
Fair value of plan assets	4,200	(3,789)
Total liabilities, net	$ 1,406	$ 1,269

5. Changes in the present value of defined benefit obligation

	2020	2019
	U.S. Dollars in thousands	
Balance at January 1,	$ 5,058	$ 4,987
Interest costs	84	133
Current service cost	264	282
Benefits paid	(102)	(1,180)
Demographic assumptions	(3)	40)
Financial assumptions	(124)	292
Past Experience	33	108
Currency Exchange	396	396
Balance at December 31,	$ 5,606	$ 5,058

6. Plan assets

a) Plan assets

Plan assets comprise assets held by long-term employee benefit funds and qualifying insurance policies.

NOTE 16: - EMPLOYEE BENEFIT LIABILITIES, NET (CONT.)

b) Changes in the fair value of plan assets

	2020	2019
	U.S. Dollars in thousands	
Balance at January 1,	$ 3,789	$ 4,200
Expected return	61	108
Contributions by employer	187	179
Benefits paid	(102)	(1,081)
Demographic assumptions	0	(4)
Financial assumptions	0	(2)
Past Experience	(28)	58
Current service cost due to the transfer of real yield from the compensation component to the royalties component in executive insurance policies before 2004	(1)	1
Currency exchange	294	330
Balance at December 31,	$ 4,200	$ 3,789

7. The principal assumptions underlying the defined benefit plan

	2020	2019	2018
		%	
Discount rate of the plan liability	1.8	2.79	2.02
Future salary increases	3.0	3.1	3.6

The sensitivity analyses below have been determined based on reasonably possible changes of the principal assumptions underlying the defined benefit plan as mentioned above, occurring at the end of the reporting period.

In the event that the discount rate would be one percent higher or lower, and all other assumptions were held constant, the defined benefit obligation would decrease by $302 thousands or increase by $356 thousands, respectively.

In the event that the expected salary growth would increase or decrease by one percent, and all other assumptions were held constant, the defined benefit obligation would increase by $343 thousands or decrease by $281 thousands, respectively.

NOTE 17: - CONTINGENT LIABILITIES AND COMMITMENTS

a. On August 23, 2010, the Company entered into a 30 years collaboration agreement with Baxter Healthcare Corporation ("Baxter") with respect to obtaining the distribution rights for Glassia. During 2015, Baxter assigned all its rights under the collaboration agreement to Baxalta US Inc. ("Baxalta") which was acquired during 2016 by Shire plc ("Shire"), which is now part of Takeda ("Takeda" and in these consolidated financial statements Baxter, Baxalta and Shire will be referred to as "Takeda").

The collaboration agreement consists of three main agreements (1) An Exclusive Manufacturing, Supply and Distribution agreement for Glassia in the United States, Canada, Australia and New Zealand (the "Territory" and the "Distribution Agreement", respectively); (2) Technology License Agreement for the use of the Company's knowhow and patents for the production, continued development and sale of Glassia by Takeda (the "License Agreement") in the Territory; and (3) A Paste Supply Agreement for the supply by Takeda of plasma derived fraction IV-1 to be used by the Company for the production of Glassia (the "Raw Materials Supply Agreement").

Pursuant to the agreements, the Company was entitled to certain upfront and milestone payments at a total amount of $45 million, and for a minimum commitment of Takeda to acquire Glassia produced by the Company over the first five years of the term of the Distribution Agreement. In addition, upon initiation of sales of Glassia manufactured by Takeda the Company will be entitled to royalty payments at a rate of 12% on net sales of Glassia through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually (the "Royalty Payments").

As of December 31, 2020, the Company received a total of $40.0 million on account of the agreed upfront and milestone payments from Takeda pursuant to the Distribution and License Agreements as amended. Prior to the October 2016 amendment of the Distribution Agreement, the net proceeds on account of the upfront the milestone payments received were recorded as deferred revenues and were recognized as revenues based on the actual sales of Glassia on a pro-rata basis. Following October 2016, the balance of the deferred revenues was recognized on a straight - line basis according to Takeda's updated minimum purchase commitment through December 31, 2018, which was the term of the supply commitment period prior to the October 2016 amendment. Non- refundable revenues due to the achievement of milestones are recognized upon reaching the milestone. The Company is entitled to the remaining unpaid balance of the millstone payment totaling $5.0 million which will be paid upon the achievement of such milestone.

Between 2013 and 2019, the parties amended the License Agreement and the Distribution Agreement to extend the supply of Glassia by the Company to Takeda and increase Takeda's minimum purchase commitment. Pursuant to the recent amendment of the Distribution Agreement entered into during August 2019, the maximum commitment by the Company to manufacture and sale Glassia to Takeda and the minimum commitment of Takeda to acquire Glassia manufactured by the Company is currently extended through the end of 2021. Based on the agreement, the Company estimates that the total revenues from sales of Glassia to Takeda for the year 2021 will be $25 million. See note 22a for information regarding 2020 revenues from sales to Takeda.

Takeda will complete the technology transfer of Glassia, and pending FDA approval, will initiate, during 2021 its own production of Glassia for distribution in the U.S. market as well as Territory. Accordingly, following the transition of manufacturing to Takeda, the Company will terminate the manufacturing and sale of Glassia to Takeda resulting in a significant reduction in revenues. Upon initiation of sales of Glassia manufactured by Takeda, Takeda will pay the Company the Royalty Payments as defined above.

Pursuant to the Distribution Agreement, Takeda is responsible to conduct any required additional clinical studies required to obtain or maintain Glassia's marketing authorization in the Territory. Under certain condition, the Company will be required to participate in the funding of these clinical studies in a total amount not to exceed $10 million.

NOTE 17: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

Pursuant to the Raw Material Supply Agreement Takeda undertook to provide the Company, free of charge, all quantities of plasma derived fraction IV-1 required by the Company for manufacturing Glassia to be sold to Takeda for distribution in the Territory. The Company accounts for the fair value of the plasma derived fraction IV-1 used and sold as revenues and charges the same fair value to cost of revenue. In addition, the Company has the right to acquire from Takeda plasma derived fraction IV-1 for its continued development and for the production, sale and distribution of Glassia by the Company outside the Territory.

b. In November 2006, the Company entered into an agreement with PARI GmbH ("PARI") in connection with a supply by the third party of a certain medical devise required for the development of the Company's Inhaled AAT product. Pursuant to the agreement, the Company was licensed to use developments made by PARI. Furthermore, PARI will provide the Company certain quantities of devices for carrying out clinical trials, free of charge. In the event that the development is successful and the underlining product obtains required marketing authorization, the Company will pay PARI royalties based on sales of the devices through the later of the device patents expiration period or 15 years from the first commercial sale of the Company's the Inhaled AAT product.

On expiration of the royalty period, the license will become non-exclusive and the Company shall be entitled to use the rights granted to it pursuant to the agreement without paying royalties or any other compensation. In addition, and according to a mechanism set in the agreement, PARI would be required to pay royalties to the Company of the total net sales of the device exceeding a certain amount, through the later of the device patents expiration period or 15 years from the first commercial sale of the Company's Inhaled AAT product.

In February 2008, the parties executed an amendment to the agreement according to which the exclusive global license granted to the Company was expanded to two additional indications. The royalties are applicable to all indications mentioned above.

In addition, the parties entered into a commercialization and supply agreement, which ensures long-term regular supply of the device, including spare parts.

In May 2019, the Company signed a Clinical Study Supply Agreement ("CSSA") with PARI for the supply of the required quantities of controller kits and the web portal associated with PARI's device required for Company's continued clinical trials with respect the its Inhaled AAT product. The CSSA is a supplement agreement to the agreement and will expire upon the expiration or termination of the agreement.

NOTE 17: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

c. In July 2011, the Company entered into a strategic collaboration agreement with Kedrion Biopharma for clinical development, marketing, distribution and sales in the United States of the Company's rabies immune globulin (Human) under the trade name KedRab. The product, is manufactured and marketed by the Company in other countries under a different trade name KamRab. The Company obtained U.S marketing approval from the FDA for KedRab in August 2017, and commercial launch of the product in the US was initiated in the beginning of 2018.

In October 2016 the parties entered into an amendment to the agreement pursuant to which the parties agreed to conduct a required post-marketing-commitment clinical study which was initiated in March 2017 and finalized during 2020. The cost of the study was equally shared between the parties.

In April 2020, the Company entered into a binding term sheet with Kedrion for the co-development, manufacturing and distribution of a human plasma-derived Anti-SARS-CoV-2 polyclonal immunoglobulin (IgG) product as a potential treatment for COVID-19 patients. The plasma-derived Anti-SARS-CoV-2 IgG product will be developed and manufactured utilizing the Company's proprietary IgG platform technology. Pursuant to the agreed terms, Kedrion will provide plasma, collected at its KEDPLASMA centers, from donors who have recovered from the virus and, upon receipt of regulatory approvals, will be responsible for commercialization of the product in the U.S., Europe, Australia, South Korea, United Kingdom, Switzerland and Norway. The Company is responsible for product development, manufacturing, clinical development, with Kedrion's support, and regulatory submissions. The Company will also assume distribution responsibility in all territories outside of those Kedrion is responsible for. Marketing rights for the product in China will be shared by the parties. The binding term sheet shall remain in full force and effect until the definitive agreements are executed by the parties, or at the latest until June 30, 2021, unless early terminated by mutual agreement of the parties.

d. In July 2019, the Company entered into a 7-year Master Clinical Services Agreement with a third party for the provision of certain clinical research services and other tasks to be performed by such third party, in connection with the Company's Phase III clinical study for its inhaled AAT product.

e. In December 2019, the Company entered into a binding term sheet for a 12-year contract manufacturing agreement with a third party to manufacture an FDA-approved and commercialized specialty hyper-immune globulin product. Following the execution of the required technology transfer from the current manufacturer, and pending obtaining all required FDA approvals, the Company is expected to commence commercial manufacturing of the product in early 2023.

As of December 31, 2020, the Company recognized an asset in respect of costs of fulfilling contract on the amount of $ 2,059 thousands. No amortization or impairment losses was recognized.

As of December 31, 2020, the Company recognized unearned amounts received in which not yet recognized as revenues.

f. In December 2019, the Company entered into an agreement with Alvotech, a global biopharmaceutical company, to commercialize Alvotech's portfolio of six biosimilar product candidates in Israel, upon receipt of regulatory approval from the Israeli Ministry of Health ("IMOH"). Pursuant to the agreement the Company is obligated to pay Alvotech certain milestone payments to Alvotech, in advance of the launch of the six biosimilar in Israel.

NOTE 18: - GUARANTEES AND CHARGES

a. The Company provided a bank guarantees in the amount of $ 272 thousands in favor of the Lessor of its leased office facility in Rehovot, Israel, and for other obligation, as guarantee for meeting its obligations under the lease agreement.

b. The Company pledged specific purchased assets as collateral against loans, in the original amount of NIS 7,585 thousand ($ 2,362 thousand) received to fund the purchase of such assets.

NOTE 19: - EQUITY

a. share capital

	December 31, 2020		December 31, 2019	
	Authorized	Outstanding	Authorized	Outstanding
Ordinary shares of NIS 1 par value	70,000,000	44,742,963	70,000,000	40,353,101

b. Movement in share capital:

Issued and outstanding share capital:

	Number of shares
Balance as of January 1, 2019	40,295,078
Issue of shares	-
Exercise of options into shares	13,133
Exercise of restricted shares	44,890
Balance as of December 31, 2019	40,353,101
Issue of shares	4,166,667
Exercise of options into shares	164,867
Exercise of restricted shares	58,328
Balance as of December 31, 2020	44,742,963

Ordinary shares of NIS 1 par value

c. Rights attached to Shares

Voting rights at the shareholders general meeting, rights to dividend, rights in case of liquidation of the Company and rights to nominate directors.

d. Share options and restricted shares share units

During 2020 and 2019, 449,093 and 67,470 share options, respectively, were exercised, on a net exercise basis, into 164,867 and 13,133 ordinary shares of NIS 1 par value each and 58,328 and 44,892 restricted share units were vested for total consideration of $17 thousand and $16 thousands, respectively.

For additional information regarding options and restricted shares granted to employees and management in 2020, refer to Note 20 below.

e. Capital management in the Company

The Company's goals in its capital management are to preserve capital ratios that will ensure stability and liquidity to support business activity and create maximum value for shareholders.

f. Issuance of ordinary shares by the Company

FIMI Opportunity Fund 6, L.P. and FIMI Israel Opportunity Fund 6, Limited Partnership (the "FIMI Funds") purchased on November 21, 2019 5,240,956 ordinary shares at a price of $6.00, representing 12.99%. On February 10, 2020, the Company closed a private placement with FIMI Opportunity Fund 6, L.P. and FIMI Israel Opportunity Fund 6, Limited Partnership (the "FIMI Funds"), a then 12.99% stockholder of the Company. Pursuant to the private placement the Company issued 4,166,667 ordinary shares at a price of $6.00 per share, for an aggregate gross proceeds of $25,000 thousands. Upon closing of the private placement, the FIMI Funds ownership represents approximately 21% of the Company's outstanding shares. Concurrently, the Company entered into a registration rights agreement with the FIMI Funds, pursuant to which the FIMI Funds are entitled to customary demand registration rights (effective six months following the closing of the transaction) and piggyback registration rights with respect to all shares held by FIMI Funds. Mr. Ishay Davidi, Ms. Lilach Asher Topilsky and Mr. Amiram Boehm, members of our board of directors, are executives of the FIMI Funds.

NOTE 20: - SHARE-BASED PAYMENT

On July 24, 2011, the Company's Board of Directors approved an unregistered share options plan. In September 2016 the Company's Board of Directors approved an amendment to the plan, to cover issuance of restricted shares ("RS") under the plan and named it the Israeli Share Award Plan ("2011 Plan").

Pursuant to the 2011 Plan, granted share options and RS generally vest over a four-year period following the date of the grant in 13 installments: 25% of the options vest on the first anniversary of the grant date and 6.25% options vest at the end of each quarter thereafter. As of 2020 granted share options and RS are vest over fore equal annual installments of 25% of the granted options.

a. Expense recognized in the financial statements

The share-based compensation expense that was recognized for services received from employees and Board of Directors members is presented in the following table:

	For the Year Ended December 31		
	2020	2019	2018
	U.S. Dollar in thousands		
Cost of revenues	$ 244	$ 364	$ 401
Research and development	184	254	224
Selling and marketing	39	63	51
General and administrative	510	482	272
Total share-based compensation	$ 977	$ 1,163	$ 948

b. Share options granted to the Company's Chief Executive Officer ("CEO")

On March 25, 2020, the Company's shareholders approved the grant of options to purchase 90,000 Ordinary Shares of the Company at an exercise price of NIS 21.34 per share and 30,000 RS to the Company's CEO. The fair value of the options and of the RSs was estimated based on the binomial option valuation model, was $166 thousands and $167 thousands, respectively.

c. Share options and Restricted shares granted to Employees and Management

1. On August 11, 2020, the Company's Board of directors approved the grant of options to purchase 70,000 Ordinary Shares of the Company at an exercise price of NIS 29.41-29.68 per share to one members of the Company's management and other employees. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated at $220 thousands.

NOTE 20: - SHARE-BASED PAYMENT (CONT.)

d. Share options granted to members of the Board of Directors

On March 25, 2020, the Company's shareholders approved the grant of options to purchase 212,000 Ordinary Shares of the Company at an exercise price of NIS 23.67 per share to the Company's Board of Directors members. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated at $356 thousands.

On December 10, 2020, the Company's shareholders approved the grant of options to purchase 10,000 Ordinary Shares of the Company at an exercise price of NIS 29.41 per share to the Company's Board of Directors member. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated at $20 thousands.

e. Change of Awards during the Year

The following table lists the number of share options, the weighted average exercise prices of share options and changes in share options grants during the year:

	2020		2019		2018	
	Number of Options	Weighted Average Exercise Price In NIS	Number of Options	Weighted Average Exercise Price In NIS	Number of Options	Weighted Average Exercise Price In NIS
Outstanding at beginning of year	2,336,554	27.87	2,445,597	29.99	2,572,372	32.47
Granted	382,000	24.36	443,800	20.64	617,825	19.02
Exercised	(449,093)	18.49	(67,470)	32.30	(53,584)	15.77
Forfeited	(608,503)	51.68	(485,373)	16.98	(691,016)	30.51
Outstanding at end of year	1,660,958	20.38	2,336,554	27.87	2,445,597	29.99
Exercisable at end of year	799,640	18.97	1,412,023	33.17	1,406,048	38.02
The weighted average remaining contractual life for the share options		4.18		3.39		3.63

The range of exercise prices for share options outstanding as of December 31, 2020 and 2019 were NIS 14.82- NIS 29.68. Exercise is by cashless method.

NOTE 20: - SHARE-BASED PAYMENT (CONT.)

f. The following table lists the number of RSs and changes in RSs grants during the year:

	Number of RSs		
	2020	2019	2018
Outstanding at beginning of year	145,896	139,706	76,512
Granted	30,000	69,725	96,308
End of restriction period	(58,328)	(18,643)	(23,572)
Forfeited	(13,049)	(44,892)	(9,542)
Outstanding at end of year	104,519	145,896	139,706
The weighted average remaining contractual life for the restricted share	4.39	2.78	3.21

g. Measurement of the fair value of share options:

The Company uses the binomial model when estimating the grant date fair value of equity-settled share options. The measurement was made at the grant date of equity-settled share options since the options were granted to employees and Board of Directors members.

The following table lists the inputs to the binomial model used for the fair value measurement of equity-settled share options for the above plan:

	2020	2019	2018
Dividend yield (%)	-	-	-
Expected volatility of the share prices (%)	30-55	23-41	25-39
Risk-free interest rate (%)	0.01 – 0.58	0.3 – 1.7	0.2-2.0
Contractual term of up to (years)	6.5	6.5	6.5
Exercise multiple	2	2	2
Weighted average share prices (NIS)	20.28-28.98	19.17-19.65	18.49-21.17
Expected average forfeiture rate (%)	1.9-5.9	2-6	1-5

NOTE 21: - TAXES ON INCOME

a. Tax laws applicable to the Company

Law for the Encouragement of Industry (Taxes), 1969

The Law for the Encouragement of Industry (Taxes), 1969 (the "Encouragement of Industry Law"), provides several tax benefits for "Industrial Companies." Pursuant to the Encouragement of Industry Law, a company qualifies as an Industrial Company if it is a resident of Israel and at least 90% of its income in any tax year (exclusive of income from certain defense loans) is generated from an "Industrial Enterprise" that it owns. An Industrial Enterprise is defined as an enterprise whose principal activity, in a given tax year, is industrial activity.

NOTE 21: - TAXES ON INCOME (CONT.)

An Industrial Company is entitled to certain tax benefits, including: (i) a deduction of the cost of purchases of patents, know-how and certain other intangible property rights (other than goodwill) used for the development or promotion of the Industrial Enterprise in equal amounts over a period of eight years, beginning from the year in which such rights were first used, (ii) the right to elect to file consolidated tax returns, under certain conditions, with additional Israeli Industrial Companies under its control, and (iii) the right to deduct expenses related to public offerings in equal amounts over a period of three years beginning from the year of the offering.

Eligibility for benefits under the Encouragement of Industry Law is not contingent upon the approval of any governmental authority. The Company believes that it currently qualifies as an industrial company within the definition of the Industry Encouragement Law. The Company cannot confirm that the Israeli tax authorities will agree that the Company qualifies, or, if qualified, that it will continue to qualify as an industrial company or that the benefits described above will be available to the Company in the future.

Law for the Encouragement of Capital Investments, 1959

Tax benefits prior to Amendment 60

The Company's facilities in Israel have been granted Approved Enterprise status under the Law for the Encouragement of Capital Investments, 1959, commonly referred to as the "Investment Law". The Investment Law provides that capital investments in a production facility (or other eligible assets) may be designated as an Approved Enterprise. Until 2005, the designation required advance approval from the Investment Center of the Israel Ministry of Industry, Trade and Labor. Each certificate of approval for an Approved Enterprise ("Certificate of Approval") relates to a specific investment program, delineated both by the financial scope of the investment and by the physical characteristics of the facility or the asset.

Under the Approved Enterprise programs, a company is eligible for governmental grants ("Grants Track"). Under the Grants Track the Company is eligible for investments grants awarded at various rates according to the development area in which the plant is located: in Development Zone A the rate is 24% and in Development Zone B the rate is 10%. In addition to the above grants, the Company is eligible to tax exemption at the first two years of the benefit period (as define below) and is subject to reduced corporate tax of 10% to 25% during the remaining five to eight years (depending on the extent of foreign investment in the Company) of the benefit period. The benefits period is limited to the earlier of 12 years from completion of the investment or commencement of production ("Year of Operation"), or 14 years from the year in which the certificate of approval was obtained.

The benefit period for part of the Company plants has ended by 2017.

NOTE 21: - TAXES ON INCOME (CONT.)

Under the Investment Law a company may elect to receive an alternative package comprised of tax benefits ("Alternative Track") instead of the above mentioned grants Track. Under the Alternative Track, a company's undistributed income derived from an Approved Enterprise is exempt from corporate tax for an initial period of two to ten years (depending on the geographic location of the Approved Enterprise within Israel which begins in the first year that the Company realizes taxable income from the Approved Enterprise following the year of operation (as define below). After expiration of the initial tax exemption period, the Company is eligible for a reduced corporate tax rate of 10% to 25% for the following five to eight years, depending on the extent of foreign investment in the Company (as shown in the table below). The benefits period is limited to 12 years from the Year of Operation, or 14 years from the year in which the certificate of approval was obtained, whichever is earlier.

Tax benefits under Amendment 60

On April 1, 2005, an amendment to the Investment Law was effected ("Amendment 60"). The amendment revised the criteria for investments qualified to receive tax benefits. An eligible investment program under the amendment will qualify for benefits as a Privileged Enterprise (rather than the previous terminology of Approved Enterprise).

Pursuant to the Amendment, to be entitled to receive the tax benefits, a company must make an investment in the Privileged Enterprise exceeding a certain percentage or a minimum amount specified in the Investments Law. Such investment may be made over a period of no more than three years ending at the end of the year in which the company requested to have the tax benefits apply to the Privileged Enterprise (the "Year of Election").

The Company received a Tax Ruling from the Israeli Tax Authority that its activity is an industrial activity and the Company will be eligible for the status of a Privileged Enterprise, provided that it meets the requirements under the ruling. The Year of Election is 2009.The Company also obtained 2012 as a Year of Election.

The duration of tax benefits is subject to a limitation of the earlier of 7 to 10 years (depending on the extent of foreign investment in the company) from the first year in which the company generated taxable income (at, or after, the year of election), or 12 years from the first day of the Year of Election. The amendment does not apply to investment programs approved prior to December 31, 2004. The new tax regime applies to new investment programs only.

NOTE 21: - TAXES ON INCOME (CONT.)

The tax benefits available under Approved Enterprise or Privileged Enterprise relate only to taxable income attributable to the specific Approved Enterprise or Privileged Enterprise, and the Company's effective tax rate will be the result of a weighted combination of the applicable rates.

Tax Exemption Period	Reduced Tax Period	Rate of Reduced Tax	Percent of Foreign Ownership
2/10 years	5/0 years	25%	0-25%
2/10 years	8/0 years	25%	25-49%
2/10 years	8/0 years	20%	49-74%
2/10 years	8/0 years	15%	74-90%
2/10 years	8/0 years	10%	90-100%

The benefits available to an Approved Enterprise and a Privileged Enterprise are conditioned upon terms stipulated in the Investment Law and the related regulations and the criteria (for an Approved Enterprise) set forth in the applicable certificate of approval. If the Company does not fulfill these conditions, in whole or in part, the benefits can be cancelled and may be required to refund the amount of the benefits, linked to the Israeli consumer price index plus interest. The Company believes that its Privileged Enterprise programs currently operate in compliance with all applicable conditions and criteria.

In the event that a company declares and pays dividends from tax-exempt income, the company will be taxed on the otherwise exempt income at the same reduced corporate tax rate that would have applied to that income. Payment of dividends derived from income that was taxed at reduced rates, but not tax-exempt, does not result in additional tax consequences to the company. Shareholders who receive dividends derived from Approved Enterprise or Privileged Enterprise income are generally taxed at a rate of 15%, which is withheld and paid by the company paying the dividend, if the dividend is distributed during the benefits period or within the following 12 years (the limitation does not apply to a Foreign Investors Company, which is a company that more than 25% of its shares owned by non-Israeli residents).

Preferred Enterprise

Tax Benefits under the 2011 Amendment

As of January 1, 2011 new legislation amending to the Investment Law was effected (the "2011 Amendment"). Pursuant to the amendment a new status of "Preferred Company" and "Preferred Enterprise", replacing the existed status of "Privileged Company" and "Privileged Enterprise". Similarly to "Beneficiary Company", a Preferred Company is an industrial company owning a Preferred Enterprise which meets certain conditions (including a minimum threshold of 25% export). However, under this new legislation the requirement for a minimum investment in productive assets was cancelled.

NOTE 21: - TAXES ON INCOME (CONT.)

Under the 2011 Amendment, a uniform corporate tax rate will apply to all qualifying income of the Preferred Company, as opposed to the former law, which was limited to income from the Approved Enterprises and Beneficiary Enterprise during the benefits period. The uniform corporate tax rate will be 7% in Development Area A, and 12.5% elsewhere in Israel.

On August 5, 2013, the "Knesset" issued the Law for Changing National Priorities (Legislative Amendments for Achieving Budget Targets for 2013 and 2014), which consists of Amendment 71 to the Encouragement Law ("the Amendment"). According to the Amendment, the tax rate on preferred income from a Preferred Enterprise in 2014 and onwards will be 9% in Development Area A, and 16% elsewhere in Israel.

The Amendment also prescribes that any dividends distributed to individuals or foreign residents from the preferred enterprise's earnings as above will be subject to tax at a rate of 20% from 2014 and onwards (or a reduced rate under an applicable double tax treaty). Upon a distribution of a dividend to an Israeli company, no withholding tax is remitted.

In December 2016, the Israeli "Knesset" amended the Investment Law. According to the amendment, effective from January 1, 2017 the tax rate on:

1. Preferred income from a preferred enterprise will be 16% (in development area A – 7.5% instead of 9%).

2. Preferred income resulting from IP in a preferred technology enterprise will be 12% (in development area A – 7.5%).

3. Preferred income resulting from IP in a special preferred technology enterprise will be 6%.

4. Any dividends distributed from technology enterprise earnings to a foreign company that qualifies the provisions that are detailed in the law, will be subject to tax at a rate of 4%.

The Company has evaluated the effect of the adoption of the Amendment on its tax position, and as of the date of the approval of the financial statements, the Company believes that it will not apply the Amendment. The Company may elect to adopt the amendment in the future.

b. Tax rates applicable to the Company (other than the applicable preferred tax)

The Israeli corporate income tax rate was 23% since 2018.

NOTE 21: - TAXES ON INCOME (CONT.)

c. Tax assessments

The Company has finalized tax assessments through the end of tax year 2015.

d. Carry forward losses for tax purposes and other temporary differences

As of December 31, 2020, the Company has carried forward losses and other temporary differences in the amount of $ 27,314 thousands. Final tax assessments for the years 2016 onwards could have an impact on the balance of carry forward tax losses for which deferred tax asset was not recognized. As of December 31, 2020, The Company did not record deferred tax asset for the remaining carry forward losses due to estimation that their utilization in the foreseeable future is not probable.

e. Uncertain tax positions

The Company analyzed uncertainty involving income taxes on its financial statements and whether it has any potential impact on the financial statements. As of December 31, 2020 and 2019, the application of IFRIC 23 did not have a material effect on the financial statements.

f. Deferred taxes:

The Company initially recorded deferred tax assets for carry forward losses and other temporary differences, as their utilization in the foreseeable future is estimated to be probable. As of December 31, 2020, The Company did not record deferred tax asset for the remaining carry forward losses due to estimation that their utilization in the foreseeable future is not probable. Below is the roll forward for deferred taxes:

	Total U.S Dollars in thousands
Balance at January 1, 2020	$ 1,311
Amount carried to profit and loss	(1,330)
Amount carried to other comprehensive income	19
Balance as of December 31, 2020	$ -

Deferred tax liabilities have not been recognized for the immaterial temporary differences associated with investments in subsidiaries because the disposal of these subsidiaries in the foreseeable future is not probable and because distributions of dividends by these companies are not subject to tax.

NOTE 21: - TAXES ON INCOME (CONT.)

g. Composition:

	Statements of financial position December 31,		Statements of profit or loss Year ended December 31,		
	2020	2019	2020	2019	2018
	U.S Dollars in thousands				
Deferred tax liabilities:					
Financial assets measured at fair value through other comprehensive income	-	(32)			
Revaluation of derivatives	-	(4)			
Deferred tax assets:					
Carryforward tax losses	-	1,330	(1,330)	(726)	(1,944)
Employee benefits	-	25			
Deferred tax income (expenses)			(1,330)	(726)	(1,944)
Deferred tax assets, net	$ -	$ 1,311			

The deferred taxes are reflected in the statement of financial position as follows:

	December 31,	
	2020	2019
	NIS in thousands	
Non-current assets	$ -	$ 1,311

h. Taxes on income

	Year ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Current taxes	$ 95	$ -	$ -
Deferred tax expenses (income)	1,330	726	(1,944)
Taxes in respect of prior years		4	(11)
Taxes on income	$ 1,425	$ 730	$ (1,955)

NOTE 21: - TAXES ON INCOME (CONT.)

i. Theoretical tax

The table below represent the reconciliation between the statutory tax rate and the effective tax rate as recorded in profit or loss

	Year ended December 31, 2020
	U.S. Dollars in thousands
Gain before taxes on income	$ 18,565
Statutory tax rate	23%
Tax calculated using the statutory tax rate	4,270
Increase (decrease) in taxes resulting from permanent differences - the tax effect:	
Adjustment of deferred tax balances following a change in tax rates	
Taxable income with preferred income tax rates by virtue of the Encouragement Law	(3,082)
Tax exempt income, income subject to special tax rates and nondeductible expenses and other	(303)
Difference between measurement basis of income/expenses for tax purposes and measurement basis of income/expenses for financial reporting purposes	441
Prior year taxes	-
Other	99
Tax on income	$ 1,425
Effective tax rate	7.7%

	Year ended December 31, 2019
	U.S. Dollars in thousands
Gain before taxes on income	$ 22,981
Statutory tax rate	23%
Tax calculated using the statutory tax rate	5,286
Adjustment of deferred tax balances following a change in tax rates	(356)
Taxable income with preferred income tax rates by virtue of the Encouragement Law	(3,747)
Tax exempt income, income subject to special tax rates and nondeductible expenses and other	(105)
Increase in unrecognized tax losses in the year	(352)
Prior year taxes	4
Tax on income	$ 730
Effective tax rate	3.2%

	Year ended December 31, 2018
	U.S. Dollars in thousands
Gain before taxes on income	$ 20,341
Statutory tax rate	23%
Tax calculated using the statutory tax rate	4,678
Increase (decrease) in taxes resulting from permanent differences - the tax effect:	
Carry-forward tax losses utilization for which no deferred taxes were provided, net	(4,678)
Temporary differences for which deferred taxes are initially recognized	(1,944)
Prior year taxes	(11)
Tax on income	$ (1,955)
Effective tax rate	9.6%

NOTE 22: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF PROFIT AND LOSS

a. Additional information about revenues

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Revenues from major customers each of whom amount to 10% or more, of total revenues			
Customer A[(1)]	$ 65,081	$ 68,138	$ 63,338
Customer B	18,290	16,369	11,779
Customer C	13,793	14,454	-
	$ 97,163	$ 98,961	$ 75,567

(1) For additional information regarding the aggregate amount of the transaction price allocated to the performance obligations that are unsatisfied, refer to note 17a.

b. Revenues based on the location of the customers, are as follows:

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
U.S.A and North America	$ 84,949	$ 84,572	$ 75,331
Israel	36,144	31,959	28,093
Europe	4,461	4,701	3,594
Latin America	6,867	3,792	3,994
Asia	766	2,067	3,336
Others	59	96	121
Total Revenue	$ 133,246	$ 127,187	$ 114,469

NOTE 22: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF PROFIT AND LOSS (CONT.)

c. Cost of goods sold

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Cost of materials	$ 54,745	$ 69,766	$ 56,156
Salary and related expenses	17,957	16,941	15,290
Subcontractors	4,876	4,451	3,633
Depreciation and amortization	3,248	2,991	2,859
Energy	1,626	1,551	1,426
Other manufacturing expenses	575	712	566
	83,027	96,412	79,930
Decrease (increase) in inventories	2,667	(18,962)	(6,933)
Total Cost of goods sold	$ 85,694	$ 77,450	$ 72,997

d. Research and development

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Salary and related expenses	$ 6,045	$ 5,897	$ 5,925
Subcontractors	4,794	5,196	2,275
Materials and allocation of facility costs	1,682	966	1,131
Depreciation and amortization	725	663	159
Others	363	337	257
Total Research and development	$ 13,609	$ 13,059	$ 9,747

For additional information regarding government grant refer to Note 13(b)

e. Selling and marketing

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Salary and related expenses	$ 1,639	1,467	1,647
Marketing support	144	103	121
Packing, shipping and delivery	750	504	477
Marketing and advertising	586	788	424
Registration and marketing fees	934	917	470
Others	465	591	491
Total Selling and marketing	$ 4,518	$ 4,370	$ 3,630

NOTE 22: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF PROFIT AND LOSS (CONT.)

f. General and administrative

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Salary and related expenses	$ 3,870	$ 3,475	3,085
Employees welfare	978	1,296	1,151
Professional fees and public company expense	3,055	2,162	2,012
Depreciation, amortization and impairment	779	717	686
Communication and software services	924	799	675
Others	533	745	916
Total General and administrative	$ 10,139	$ 9,194	$ 8,525

g. Financial expense(income)

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Financial income			
Interest income and gains from marketable securities	$ 1,027	$ 1,146	$ 830
Financial expense			
Fees and interest paid to financial institutions	266	293	172
Financial income and (expense)			
Derivatives instruments measured at fair value	(1,097)	(512)	504
Translation differences of financial assets and liabilities	(438)	(139)	98
Bond securities measured at fair value	102	(5)	(178)
Total Financial expense(income)	$ (672)	$ 197	$ 1,082

NOTE 23: - INCOME (LOSS) PER SHARE

a. Details of the number of shares and income (loss) used in the computation of income (loss) per share

	Year Ended December 31,					
	2020		2019		2018	
	Weighted Number of Shares	Income Attributed to equity holders of the Company	Weighted Number of Shares	Income Attributed to equity holders of the Company	Weighted Number of Shares	Loss Attributed to equity holders of the Company
		U.S. Dollars in thousands		U.S. Dollars in thousands		U.S. Dollars in thousands
For the computation of basic income (loss)	44,140,771	$ 17,140	40,320,888	$ 22,251	40,275,374	$ 22,296
Effect of potential dilutive ordinary shares	449,107	-	260,739	-	170,043	-
For the computation of diluted income (loss)	44,589,878	$ 17,140	40,581,627	$ 22,251	40,445,417	$ 22,296

b. The computation of the diluted income per share for the years ending December 31, 2020, 2019 and 2018 took into account the options and RSs due to their dilutive effect.

NOTE 24: - OPERATING SEGMENTS

a. General

The operating segments are identified on the basis of information that is reviewed by the chief operating decision makers ("CODM") to make decisions about resources to be allocated and assess its performance. Accordingly, for management purposes, the Company is organized into operating segments based on the products and services of the business units and has two operating segments as follows:

Proprietary Products	Development, manufacturing, sales and distribution of plasma-derived protein therapeutics.
Distribution	Distribute imported drug products in Israel, which are manufactured by third parties.

Segment performance is evaluated based on revenues and gross profit in the financial statements.

The segment results reported to the CODM include items that are allocated directly to the segments and items that can be allocated on a reasonable basis. Items that were not allocated, mainly the Company's headquarter assets, research and development costs, sales and marketing costs, general and administrative costs and financial costs (consisting of finance expenses and finance income and including fair value adjustments of financial instruments), are managed on a Company basis.

The segment liabilities do not include loans and financial liabilities as these liabilities are managed on a group basis.

NOTE 24: - OPERATING SEGMENTS (CONT.)

b. Reporting on operating segments

	Proprietary Products	Distribution	Total
	U.S. Dollars in thousands		
Year Ended December 31, 2020			
Revenues	$ 100,916	$ 32,330	$ 133,246
Gross profit	$ 43,166	$ 4,386	$ 47,552
Unallocated corporate expenses			(28,315)
Finance income, net			(672)
Income before taxes on income			$ 18,565

	Proprietary Products	Distribution	Total
	U.S Dollars in thousands		
Year Ended December 31, 2019			
Revenues	$ 97,696	$ 29,491	$ 127,187
Gross profit	$ 45,271	$ 4,466	$ 49,737
Unallocated corporate expenses			(26,953)
Finance income, net			197
Income before taxes on income			$ 22,981

	Proprietary Products	Distribution	Total
	U.S. Dollars in thousand		
Year Ended December 31, 2018			
Revenues	$ 90,784	$ 23,685	$ 114,469
Gross profit	$ 37,988	$ 3,484	$ 41,472
Unallocated corporate expenses			(22,213)
Finance expense, net			1,082
Loss before taxes on income			$ 20,341

NOTE 25: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES

a. Balances with related parties

	December 31, 2020	December 31, 2019
	U.S. Dollars in thousands	
Other accounts payables	$ 129	$ 151
Trade receivable	$ 1,429	$ -

NOTE 25: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

b. Transactions with employed/directors that accounts as related parties

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Salary and related expenses to those employed by the Company or on its behalf	$ -	$ 311	$ 352
Remuneration of directors not employed by the Company or on its behalf	$ 506	$ 363	$ 366
Number of People to whom the Salary and remuneration Refer:			
Related and related parties employed by the Company or on its behalf	-	2	2
Directors not employed by the Company	9	7	8
Total Directors employed and not employed by the Company	9	9	10

c. Transactions with key executive personnel (including non-related parties)

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Short-term benefits	$ 3,237	$ 3,157	$ 2,766
Share-based payment	457	506	285
Total	$ 3,694	$ 3,663	$ 3,051

d. Transactions with related parties

	Year Ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
Revenues	$ 3,899	$ 2,566	$ 3,529
Cost of Goods Sold	$ 255	$ 13	$ -
Selling and marketing expenses	$ 0	$ 257	$ 313
General and administrative expenses	$ 522	$ 447	$ 408

NOTE 25: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

e. Terms of Transactions with Related Parties

Sales to related parties are conducted at market prices. Open account that have yet to be repaid by the end of the year by a related party bear no interest and their settlement will be in cash and certain balances are guaranteed by letter of credit. For the years ended December 31, 2020, 2019 and 2018, the Company recorded no allowance for doubtful accounts for trade receivable from related parties.

1. On May 26, 2011, the Company entered into an amended agreement with Tuteur SACIFIA ("Tuteur"), a company registered in Argentina, currently under the control of the Hahn family. Such amended agreement revises and replaces the distribution agreement signed in 2001 between the Company and Tuteur in connection with the distribution of Glassia in Argentina and Paraguay. The amended agreement was made as an arm's length transaction. On August 19, 2014 the Company entered into a subsequent amendment to the agreement, pursuant to which, the Company granted Tuteur distribution right in Argentina for its KamRho(D) product. In addition the distribution territory and expanded to include Bolivia.

   Pursuant to the distribution agreement, Tuteur serves as the exclusive distributor of Glassia and KamRho(D), in Argentina, Paraguay and Bolivia. In 2016 the Board of Directors approved a marketing contribution funding to Tuteur for reimbursement of costs associated with marketing activities aimed to locating new AATD patients and increasing the overall number of AATD patients treated with Glassia in Argentina. Such funding was paid by the Company in each of 2016 and 2017. In addition, in 2016 and in 2017 the Board of Directors approved extending a price discount for KamRho (D) to Tuteur.

   During 2018, a third amendment to the agreement was executed, which was effective as of July 1, 2018, pursuant to which the Company extended a price discount for Glassia. Pursuant to the third amendment Tuteur was obligated to issue bank guarantees to cover any future outstanding debt due to supply of products by the Company to Tuteur.

   In May 2020 the Company and Tuteur entered into new agreement pursuant to which Tuteur serves as the exclusive distributor of GLASSIA and KamRho(D) IM and IV in Argentina, Paraguay, Bolivia and Uruguay. The agreement includes minimum annual purchase commitments by Tuteur for an initial 12 month period, with respect to sales of any products in territories where registration has been completed, commencing as of the effective date of the agreement and with respect to sale of any products in the other territories, commencing the first year following the registration of any such product in the applicable territory.

2. On July 29, 2015 the Company entered into a distribution agreement with Khairi S.A. ("Khairi"), a company held, inter alia, by Mr. Leon Recanati, the Chairman of the Company's Board of Directors, and Mr. Jonathan Hahn, a director of the Company and his siblings, for the distribution of Glassia and KamRho(D) in Uruguay. This distribution agreement with Khairi is an arm's length transaction. For the years ending December 31, 2019, 2018 and 2017 there were no sales of Glassi and KamRho(D) by the Company to Khairi. The agreement was expired on December 31, 2020.

3. FIMI Opportunity Fund 6, L.P. and FIMI Israel Opportunity Fund 6, Limited Partnership (the "FIMI Funds") purchased on November 21, 2019 5,240,956 ordinary shares at a price of $6.00, representing 12.99%. On February 10, 2020, the Company closed a private placement with FIMI Opportunity Fund 6, L.P. and FIMI Israel Opportunity Fund 6, Limited Partnership (the "FIMI Funds"), a then 12.99% stockholder of the Company. Pursuant to the private placement the Company issued 4,166,667 ordinary shares at a price of $6.00 per share, for an aggregate gross proceeds of $25,000 thousands. Upon closing of the private placement, the FIMI Funds ownership represents approximately 21% of the Company's outstanding shares. Concurrently, the Company entered into a registration rights agreement with the FIMI Funds, pursuant to which the FIMI Funds are entitled to customary demand registration rights (effective six months following the closing of the transaction) and piggyback registration rights with respect to all shares held by FIMI Funds. Mr. Ishay Davidi, Ms. Lilach Asher Topilsky and Mr. Amiram Boehm, members of our board of directors, are executives of the FIMI Funds.

   The following Israeli entities: Amnir recycling industries Ltd., Grafity office equipment marketing, G-one security solutions, Carmel Frenkel IND, and Oxygen & Argon works Ltd who are controlled by or affiliated with the FIMI Funds, are currently engaged by the Company for the provision of certain services relating to its continuous operations in non-material amounts and in market prices.

NOTE 25: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

f. CEO employment terms

On December 20, 2018 the Company's shareholders approved an amendment to the employment terms of the Company's CEO. Pursuant to the amendment the CEO monthly gross salary increased to NIS 82,500 (or $22,627), effective as of July, 1 2018. On March 2020 the Company's shareholders approved an amendment to the employment terms of the Company's CEO, pursuant to which, the monthly gross salary will increased to NIS 88,000 (or $25,462), effective as July 1, 2019.

During 2020 the Company accounted for a bonus accrual to the CEO in the amount of $ 194 thousands. As for a grant of options and restricted shares to the CEO, refer to Note 20b.

NOTE 26: - EVENTS SUBSEQUENT TO THE REPORTING PERIOD

a. On January 31, 2021 the Company entered into an agreement for the acquisition of the plasma collection center and certain related rights and assets from the privately-held Blood and Plasma Research, Inc (B&PR) of Beaumont, TX, USA. B&PR's collection facility primarily specializes in the collection of hyper-immune plasma used for the Anti-D immunoglobulin, which is manufactured by the Company and distributed in international markets.

The acquisition for a total consideration of approximately $1.63 million, is expected to be consummated during the first quarter of 2021, subject to closing conditions as set forth in the acquisition agreement, through Kamada Plasma LLC, a newly formed wholly owned subsidiary of Kamada, which will operate the plasma collection activity in the U.S..

Exhibit 4.33

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

[*****] indicates the redacted confidential portions of this exhibit.

DISTRIBUTION AGREEMENT

This Agreement is made and entered into as of May 20, 2020 (the "**Effective Date**") by and between:

Kamada Ltd., a company duly incorporated and registered under the laws of the State of Israel, with principal offices at 2 Holzman Street, Weizmann Science Park, Rehovot 7670402, Israel (the "**Supplier**")

and

TUTEUR S.A.C.I.F.I.A., a corporation organized under the laws of Argentina, having its registered office at Av. Juan de Garay 848, 1153 Buenos Aires, Argentina (the "**Distributor**").

RECITALS

WHEREAS, on August 2, 2011, Supplier and Distributor entered into a distribution agreement amending and restating a distribution agreement entered into in November 2001;

WHEREAS, such distribution agreement as amended, expired on December 31, 2019, the Supplier wishes to re-appoint the Distributor, and the Distributor wishes to be re-appointed and act as the Supplier's distributor of the Products in the Territory, all subject to the terms and conditions set forth hereinafter (capitalized terms shall have the meanings ascribed to them hereinafter);

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and intending to be legally bound hereby, the Parties agree as follows:

1. Definitions

Unless otherwise explicitly said, when used in this Agreement the following capitalized terms shall have the meanings ascribed to them hereinafter:

1.1. The **"Indications"** – the indications for which the Products shall be marketed and sold by the Distributor in the Territory as set forth in **Appendix A**.

1.2. The **"Product(s)" –** the product(s) listed in **Appendix A**.

1.3. The **"Territory"-** the territory defined in **Appendix B.**

1.4. The **"Trademarks"** – the trademarks under which the Products shall be marketed and sold by the Distributor in the Territory as set forth in **Appendix A**.

2. Grant of License

2.1. The Supplier hereby grants to the Distributor the exclusive right to promote, market, distribute, register, sell, advertise and apply for tenders for the distribution and sale of the Products in the Territory, solely under the corresponding Trademarks and for the corresponding Indications, during the term hereof and subject to the terms and conditions of this Agreement.

2.2. The Distributor shall not, directly or indirectly, seek customers, establish a branch, or maintain any distribution depot for the purpose of pursuing an active promotion, advertising or selling policy for the Products outside of the Territory or set up a base to do so; or market, distribute, sell or advertise the Products for any indication other than the Indications; or knowingly sell or advertise the Products to any third party who the Distributor has reason to believe intends to sell the Products outside the Territory. This obligation shall be limited to those territories and/or those uses with respect to which the distribution rights have been or shall be exclusively allocated by the Supplier to a third party or have been or shall be reserved by the Supplier.

2.3. The Distributor shall, at its sole responsibility and liability, be entitled to appoint sub-distributors or agents for the sale of the Products in the Territory, provided that:

2.3.1. The Distributor informs the Supplier in advance of the identity of any such sub-distributor or agent that it wishes to appoint, and obtains Supplier's prior written consent to each such appointment;

2.3.2. the Distributor furnishes the Supplier with a copy of each agreement between the Distributor and any such sub-distributor or agent, as the case may be, and that the any such agreement is consistent with the terms and conditions of this Agreement, and provides that it should be automatically terminated upon termination or expiration of this Agreement;

2.3.3. The sub-distributor shall sign a Release Letter in the form attached hereto as **Appendix H**, if the sub-distributor is handling the registration of the Products or receives the Marketing Authorization for the Product(s);

2.3.4. the Distributor undertakes to be liable for any and all acts and/or omissions of the said sub-distributor or agent; and

2.3.5. all orders and payments to the Supplier for the Products distributed or sold by such sub-distributors and agents remain under the sole responsibility of the Distributor.

3. Distributor's Functions and General Obligations

Distributor shall:

3.1. use its best efforts to promote the sale of the Products in the Territory in accordance with the Supplier's policy, as shall be informed to the Distributor by the Supplier from time to time, and shall protect the Supplier's interests with the diligence of a responsible businessman;

3.2. without derogating from Section 2.1, participate in, and submit bids including the Products with respect to public tenders in the Territory;

3.3. purchase the Products directly and solely from the Supplier, and not from any other source;

3.4. maintain sufficient inventory of the Products in the Distributor's warehouses equal to the higher between (i) three (3) months' supply (defined, per each of the Products, as the Distributor's average quarterly sales of such Product over the preceding twelve (12) months) or (ii) the Distributor's average quarterly sales forecast for that year;

3.5. ensure and maintain suitable warehousing and freight conditions, as required pursuant to the Products' specifications and the Supplier's instructions;

3.6. make no representation or warranty with respect to the Products beyond the statements in the Supplier's label for the Products as approved by the competent regulatory authorities, unless such representation or warranty is specifically authorized in advance and in writing by the Supplier;

3.7. take no negligent or willful action, which might adversely affect the standing of the Supplier;

3.8. process all orders, and effect all dispatches of the Products;

3.9. promptly inform the Supplier of any communication received from any competent regulatory authority in the Territory relating to the Products, and of any adverse reaction and complaint of which it becomes aware, and shall consult with the Supplier as to all responses thereto;

3.10. translate from English language, at its own cost, into the local languages any documentation related to the marketing and/or sale of the Products in the Territory;

3.11. obtain and maintain in a timely manner, at its own cost, all necessary consents and approvals necessary for the importation, marketing, distribution and sale of the Products in the Territory;

3.12. not use any of the Products, or knowingly supply any of the Products to any third party for use, in any clinical or other study, without receiving the prior written consent of the Supplier.

4. Registration of the Product and Regulatory Requirements

The following section shall apply with respect to any Product that has to be registered and approved for marketing authorization by the competent regulatory authorities in the Territory.

4.1. Marketing authorization and/or registration of the Product shall be applied for and will be made by the Distributor, in the name of the Supplier (if permitted by local regulations) with respect to each Product that is not already registered and approved for marketing by the competent regulatory authorities in the Territory, at the Distributor's sole expense. In case it is not permitted to apply for the marketing authorization and/or registration of the Product in the name of the Supplier, the application shall be made in the name of the Distributor as a Marketing Authorization Holder ("MAH"), provided that the ownership at the marketing authorization and/or registration of the Product shall remain with Supplier as per Section 4.8 below.

4.2. The Distributor shall inquire and inform the Supplier in writing of all regulatory registration procedures under the local law and regulations, which are required in order to register, market and sell the Product in the Territory. The Distributor shall give guidance in writing to the Supplier, upon Supplier's request, as to which documentation and or/regulatory requirement is required from the Supplier for this purpose. To the extent that the Distributor is not familiar with the applicable regulatory requirements with regard to any of the Products, the Distributor shall be obligated to receive consultation in order to comply with the local regulatory requirements for such Product, at its sole cost and expense.

4.3. The Distributor shall review the dossier and additional documentation (the "**Marketing Authorization Documents**") provided to it by the Supplier and advise the Supplier within thirty (30) days to the extent that any further documentation is needed for the registration of the Product.

The Distributor shall use the aforesaid Marketing Authorization Documents solely for the purpose of the registration and for obtaining a marketing authorization of the corresponding Product for the Indications in the Territory.

4.4. The Distributor shall translate from English, at its own cost, into the local languages, the packaging material and/or any documentation related to the registration of the Product in the Territory.

4.5. The Distributor shall provide the Supplier with a copy of the final registration file and the final Marketing Authorization Documents that are to be filed with the competent authorities, with an English translation thereof. The Supplier shall review the final file to be approved for submission.

4.6. Upon receipt of Supplier's approval, the Distributor undertakes to file the Marketing Authorization Documents to the competent regulatory authorities in the Territory within one (1) month following its receipt thereof from the Supplier. All fees and related expenses shall be solely borne by the Distributor.

4.7. The Distributor shall not apply for any tender and shall not commence sales of any of the Products in the Territory before all required processes of Marketing Authorization have been completed, if required under applicable law in the Territory, and shall maintain in force during the term hereof all licenses, approvals and permits necessary for the marketing and sale of the Products in the Territory.

4.8. The Supplier shall be the sole owner of any and all registration files and marketing approvals for the Product in the Territory and of any application for permission and any permission to market, advertise and sell the Products in the Territory, or – in the event that applicable law in the Territory requires that the Distributor will be named as an owner of the registration file and/or application and/or permission to market, then, upon expiry or termination of this Agreement for any reason whatsoever, the registration file of the Product and any and all approvals, including pending applications, shall revert solely to the Supplier or to the Supplier's designee, and the Distributor shall not have any right to receive any compensation in respect thereof, except that this Agreement is terminated with cause by Distributor due to Supplier's breach of this Agreement, in which case Distributor shall be entitled to be reimbursed for all reasonable and customary out of pocket expenses incurred in order to obtain the marketing authorization. Upon execution of this Agreement, the Distributor shall sign a Release Letter in the form attached hereto as **Appendix H**.

4.9. If Distributor fails to register any of the Products in the Territory within twelve (12) months after receiving by the Distributor of all Marketing Authorization Documents for reasons attributable to the Distributor, the Supplier shall have the right to terminate this Agreement or the exclusivity granted to Distributor herein, with respect to such Product or with respect to all the Products, by a written notice to the Distributor.

4.10. The Distributor shall bear all costs associated with the registration of the Product with the competent regulatory authorities in the Territory (including, without limitation, all costs associated with the grant of the marketing authorization, health authority fees, translation fees, taxes and variation fees, product samples purchase and testing, as well as any related fees regarding the use of consultants required to perform local submissions at the health authorities). All fees related to maintenance of the registration and marketing approvals of the Products in the Territory during the term hereof shall be solely borne by the Distributor. In the event that an audit of the competent authorities will be required under local regulation at the Supplier's premises, the Distributor shall allocate a qualified representative on its behalf to participate in such audit at its sole cost and expenses.

4.11. The Distributor shall not make any alterations to the marketing authorization, without written approval from the Supplier.

4.12. The Distributor shall keep the Supplier regularly informed in writing about all material regulatory processes and updates including: (i) the progress of the registration and other filings processes; (ii) any queries that were submitted by the competent regulatory authorities within ten (10) days after receiving such queries; (iii) any assessment reports and; (iv) regulatory guidelines relevant for the Supplier's Product and for all approvals received, as soon as reasonably practicable after the receipt of the same from the relevant regulatory authority.

5. Marketing, Advertising and Fairs

5.1. The Distributor shall prepare and provide the Supplier, within thirty (30) days from completing the registration of the Products or any of them with any competent regulatory authority in the Territory and at least three (3) months prior to commencement of each calendar year thereafter, with a detailed marketing plan, which shall include, inter alia, marketing and advertising program, tenders it intends to attend and sales forecast of the Products for the forthcoming year (the "**Marketing Plan**"). The Marketing Plan shall be subject to the Supplier's prior written approval.

5.2. The Marketing Plan shall comply with the Supplier's product and company image and marketing and advertising policy, of which the Distributor shall be informed, from time to time.

5.3. Without derogating from the foregoing, the Distributor shall submit to the Supplier, for approval, all advertising and promotional material and ensure, prior to publication or use, that it is in full compliance with all regulatory and local requirements, including Ministry of Health, and pharmaceutical regulations and of a high professional pharmaceutical standard.

5.4. The Distributor shall participate and present the Products in exhibitions, professional conferences and trade fairs in the Territory, in accordance with the Marketing Plan and as shall be agreed upon from time to time between the parties. All costs and expenses related to such participation shall be solely borne by the Distributor.

6. Legal and Regulatory Requirements

6.1. The Distributor shall comply with all legal and regulatory requirements applicable to all registration activities, marketing, distribution, sale or use of the Products in the Territory, and shall promptly inform the Supplier of any such legal requirements and any changes and developments to such legal requirements.

6.2. The Supplier shall not be liable, and the Distributor shall be solely responsible for, any payment of any fine or other penalty imposed by any competent legal and regulatory authority in the Territory, in respect of, or in connection with, all registration activities, importation, storage, promotion, marketing, distribution, sale or use of the Products, except if such fine or other penalty is imposed as a result of Supplier's misconduct or negligence, or as a result of quality problems of the Products attributable to the Supplier.

7. Orders & Supply

7.1. Within thirty (30) days following the execution hereof and on a quarterly basis thereafter, and within 14 (fourteen) days upon Supplier's written request, the Distributor shall submit to the Supplier a non-binding rolling forecast of the quantity of the Products that the Distributor plans to purchase, including its anticipated tender requirements, should it be awarded orders in any tender, during the next consecutive four (4) calendar quarters and a proposed delivery schedule.

7.2. In any respective Marketing Year during (as defined below) the term of this Agreement, The Distributor shall place written irrevocable purchase orders for such Products no later than four (4) months prior to the requested delivery date. Every order shall be subject to the Supplier's written confirmation.

7.3. The Distributor undertakes that orders placed by it will indicate a minimum amount of vials per shipment as indicated in **Appendix C**.

7.4. The Supplier shall make its best efforts to supply the ordered Products, based on the Supplier's approval of the relevant purchase order and delivery schedule.

7.5. The Products will be packed in such a manner as the Supplier considers appropriate and in compliance to the regulations of the Territory, which will be informed by the Distributor to Supplier in advance, and will be approved by Supplier .

7.6. It is understood and agreed that all sales made by the Supplier to the Distributor pursuant to the terms of this Agreement are final sales and are not sales on consignment. The Supplier shall not be required to accept the return of any Product for refund or credit, and no right of return is granted to the Distributor, except for rejections as set forth in Section 10 and 11 below.

7.7. The Distributor will promptly inform the Supplier of any tender related to the Products, in which the Distributor is not entitled or is unable to directly participate. In this case the Supplier may bid the Products for such tender, either directly or through any third party, and the Distributor shall be entitled to a commission with respect to the sale of the Products within the framework of such tender as shall be agreed in writing between the parties.

8. Minimum Annual Purchase

8.1. The Distributor irrevocably undertakes that during the first year following the registration of any of the Products in the Territory (with respect to Products that have not been registered in the respective Territory), it will place orders for, purchase and pay for, the minimum quantity of the respective Product as will be specified in **Appendix 'D'** hereto prior to registration of the respective Product. With respect to registered and marketed Products – Distribution's obligations to place orders for, purchase and pay for, the minimum quantity of the respective Product, shall commence as of the Effective Date, as per **Appendix 'D'**.

8.2. Prior to the commencement of each twelve (12) month period subsequent to such first year (a **"Marketing Year"**), the parties shall negotiate in good faith and agree in writing, with respect to each registered Product, on the minimum quantity to be purchased by the Distributor in the forthcoming Marketing Year, and the Distributor undertakes to purchase and fully pay for such minimum quantity.

The minimum quantity that the Distributor is obliged to purchase and pay for pursuant to this Section 8.2 or Section 8.1 above shall be hereinafter referred to as the **"Minimum Quantity"**.

8.3. If the Distributor fails to purchase and pay for the Minimum Quantity in any given Marketing Year, the Supplier shall be entitled, at its sole discretion and subject to a thirty (30) days prior written notice to the Distributor: (i) to terminate this Agreement on a Product by Product basis, or (ii) to cancel the exclusivity granted to the Distributor hereunder, and/or narrow the scope of the Territory, if applicable, on a Product by Product basis.

8.4. For the purposes of this Section 8, rejected Purchase Orders by Supplier due to an inventory shortage of any respective Product shall be accounted as Products deem to be accounted under the Minimum Quantity by Distributor, provided that in a case of an inventory shortage of any respective Product, the parties will act in good faith in order to coordinate an alternative date for the supply of the Product by Supplier. This section is subject to the mechanism set forth under Section 7.

9. Purchase Price & Terms of Payment

9.1. During the term of this Agreement, the Distributor shall pay Supplier for the Products, the Minimum Supply Price specified under **Appendix A.** The Distributor acknowledges that the Minimum Supply Price was determined, among other parameters, based on Distributer commitment to acquire such Minimum Quantity of the Product in each Territory as specified in **Appendix D**.

For the purposes of this Section:

"**Net Price**" means for a specified period, the total Product revenue of Distributor for sales of the Product in the Territory by Distributor to independent third party wholesalers or other customers, who are not affiliates of Distributor in the Territory, less: (a) customary and reasonably discounts and rebates as actually given to such third party customers (b) VAT; (c) transport and insurance costs; (c) amounts actually repaid or credited by reason of rejection or return of any previously sold Product; and (d) any governmental charges imposed upon Product sales, including turnover tax, debit and credit tax in accordance with law No. 25,413. The revenue records of Distributor will be according to International Financial Reporting Standards ("IFRS") except for the conversion of the Net Price from Argentine Peso to United States dollars shall be performed at the retail exchange rate informed by the Banco de la Nación Argentina for the close of business of the date prior to the actual payment of each invoice issued by Distributer during the relevant Marketing Year.

"**Transfer Price**" means the percentage (%) of the average Net Price for each Product for the previous Marketing Year as set forth in **Appendix A**. For the avoidance of doubt it is specifically noted that The Transfer Price shall not be lower than the Minimum Supply Price as set forth in **Appendix A**.

9.2. The parties will conduct a true-up mechanism once a year, as follows: within 15 days of the end of each Marketing Year, and following the end of each calendar quarter during the term for informative purpose, the Distributer shall provide a report to Supplier indicating the total quantity of Product sold in each respective Territory and the Net Price (as defined below) of that Marketing year. The report will also inform the number of vials sold but pending actual payment by customers. Based on such provided report the Parties will calculate the relevant Transfer Price (as defined below) for that Marketing Year. To the extent that the calculated Transfer Price for a given Marketing Year is higher than the Minimum Supply Price for that given year (as set forth in **Appendix A**), then, in addition to any other payments due to Supplier with respect to such Marketing Year, Supplier will be entitled to an annual supply price True-Up Payment in an amount equal to the result of the following formula:

(A-B)*C

Whereby:

A – Prior Marketing Year Transfer Price

B – Prior Marketing Year Minimum Supply Price; and

C – Total number of vials of Product supplied by Supplier to Distributer during the prior Marketing year

Such annual supply price true up amount will be separately invoiced by Supplier (Such mechanism is referred as **"Annual Minimum Supply Price True-Up Mechanism").**

9.3. Commencing on the third Marketing Year of each Product in Each Territory and no more often than once in any Marketing Year, either party may request to negotiate the Minimum Supply Price of each Product in each Territory. No change to the Minimum Supply Price shall be valid unless explicitly agreed upon in writing by the parties.

9.4. The parties agree that if any investigation is started and/or any fine or penalty is imposed to Distributor by any Argentine authority, including Argentine Customs for any reason directly or indirectly related to the Annual Minimum Supply Price True-Up Mechanism specified in section 9.2 above, Supplier shall reimburse Distributor 50% (fifty percent) of (i) all out of pocket expenses resulting from such investigation (including legal fees), (ii) any fine or penalty imposed to the Distributor; and (iii) any additional taxes or duties claimed by authorities to Distributor including applicable interest. The reimbursement shall be performed within 10 (ten) days as from the date in which Supplier has received a notice from Distributor claiming the relevant reimbursement to Supplier.

Supplier's reimbursement under this Section 9.4, is subject to the provision by Distributor of all proven supporting documents pertaining to such expenses, fines and penalties imposed by Distributor.

9.5. Distributor shall pay Supplier in full for each Invoice in US Dollars within ninety (90) days from AWB date.

9.6. The Distributor will issue a bank guarantee (from a U.S., Israeli or a western Europe bank) for every new order of the Product. Such bank guarantee would be in the value of each order and would be provided prior to the shipment of the Product from Supplier and be extended through the complete payment of the amount due on such given order/shipment.

9.7. To the extent that the Supplier received a credit line approval from the Israeli Credit Insurance Company – then the Supplier shall be able to grant a credit line to the Distributor at the approved credit amount, which may replace the payment methods above up to such credit amount, as long as such credit line is in effect.

9.8. Any overdue payment hereunder shall bear interest at the rate of 1.5% (one and a half percent) per each month in which the payment is in arrears, this without derogating from any other remedy to which the Supplier might be entitled to under this Agreement or applicable law.

9.9. All payments due to the Supplier hereunder shall be made in US Dollars, unless the Supplier instructs the Distributor otherwise, and shall be net, and free of any and all taxes, duties, levies, assessments, deductions, set-offs and/or withholdings of any nature. All banking charges will be on the account of the Distributor.

9.10. If any reduction is required to be made under applicable law, then the gross payment due to the Supplier shall be increased so that the net amount received by the Supplier following the required reduction shall be equal to the invoice amount with the addition of any accumulated interest, if due.

9.11. For the purpose of economical evaluation, the Distributor shall provide financial information to insurers and/or business data agencies, if requested by the Supplier to do so.

10. <u>Delivery; Acceptance & Rejection</u>

10.1. The Products shall be delivered to the Distributor on CIP, Buenos- Aires Airport, basis (incoterms 2010). Accordingly, the Distributor bears all risks of loss of, or damage to the goods, from the time they have been delivered to the contracted carrier at Ben-Gurion Airport, Israel.

For the avoidance of doubt, except as specifically indicated under the terms of this Section 10, the Supplier shall incur no obligation with respect to Products comprising any particular shipment, from and after the time when such Products are handed over to the Distributor's responsibility in accordance with the terms of this Section 10.

10.2. Acceptance of all Products' deliveries shall be subject to Distributor's inspection and approval, as for the compatibility of such Products with their respective specifications, which specifications are set forth in **<u>Appendix E</u>** (the "**Products Specifications**").

10.3. Subject to the Distributor providing the Supplier with conclusive written evidence and reasons, the Distributor shall have the right, for a period of thirty (30) business days following delivery, to reject or revoke the prior acceptance of any Products which: (i) fail to conform with the Products Specifications; or (ii) are recalled by the Supplier for a reason for which the Distributor is not at fault.

10.4. Subject to the Supplier's prior written approval, or at the Supplier's request and expense (in the event of a recall), the Distributor shall return any such Products rejected pursuant to the provisions of Section 10.3 to the Supplier. In a case that the defected or recalled Products cannot be returned and need to be destroyed, the Supplier will cover the reasonable and customary destruction expenses.

10.5. In the event that a dispute arises between the parties concerning whether a shipment of Products conforms to the Product Specification, the applicable Products will be submitted to an independent testing laboratory to be agreed by both parties. The cost of such test shall be borne by the party with whose results the independent laboratory shall have disagreed. Until such dispute is resolved, the Distributor shall retain and preserve the Products in question and shall not dispose thereof except with the Supplier's prior written approval.

10.6. The Distributor's failure, within thirty (30) business days of delivery, to reject or revoke acceptance of any shipment of the Products shall be conclusively deemed to constitute acceptance of such Products in good and saleable condition.

10.7. Release of any Products by the Distributor to sub-distributors or to end-customers shall be conclusively deemed to constitute acceptance of such Products in good and saleable condition.

11. <u>Complaints and Recalls</u>

11.1. Without derogating from the generality of Section 3.9 above, the Distributor will immediately notify the Supplier in writing of any complaint drawn to its attention (or to the attention of its sub-distributor or agent) by any customer regarding the Products, and shall support such notification by sending relevant documents and samples to the Supplier.

11.2. The Distributor will notify the customers, as soon as it is specifically requested to do so by the Supplier, regarding any recall, initiated by the Supplier, of any Product sold to them. Furthermore, the Distributor shall, at the Supplier's request, implement any recall of any of the Products, and the Supplier shall provide Distributor with the quantities of the recalled Products or shall refund the Distributor for the recalled Products. The Supplier will bear the reasonable and customary out of pocket expenses incurred by the Distributor as a result of the recall, initiated by the Supplier; provided that the Distributor will present Supplier the respective invoices, if applicable, evidencing such Distributor's reasonable and customary out of pocket expenses as a result of the recall initiated by the Supplier The Distributor shall notify the Supplier concerning the state of the batch recalled (i.e. the quantity of Products sold out of such batch, if any, and the quantity left at the Distributor's warehouse and unused Product's quantity at end customer's warehouse).

11.3. Without derogating from the generality of Section 3.9 above, the Distributor shall notify the Supplier of any recall procedure regarding any of the Products, initiated by the local health authorities in the Territory and of the reasons for such recall, and shall provide the Supplier with samples of the Product recalled at Supplier's customary and reasonably expenses. The Distributor shall not initiate a recall independently, without the prior written consent of the Supplier.

11.4. Without derogating from the aforesaid, the Distributor shall maintain at all times, in written or recorded form, an effective system for recall from the market of Products, and the Supplier shall be free to inspect the Distributor's recall system upon prior notice to the Distributor.

12. Reports

12.1. The Distributor shall keep the Supplier regularly informed in writing about general market conditions and the state of competition with the Products in the Territory, and provide the Supplier, subject to all applicable legal limitations, with general information on the Products' end customers. Without derogating from the foregoing, the Distributor shall fully and in a timely manner respond to all reasonable requests for information made by the Supplier.

12.2. The Distributor shall exercise due diligence to keep the Supplier informed in writing about:

12.2.1. the laws and regulations applicable in the Territory in relation to the Products (e.g., import regulations, labeling, health and safety requirements, reimbursement, etc.); and

12.2.2. to the extent relevant to the Supplier, the laws and regulations applicable to the Distributor's activities hereunder.

12.3. The Distributor shall submit to the Supplier quarterly written reports, and within thirty (30) days from the expiration or termination hereof – a final report, in which the Supplier shall be informed, inter alia, of the status of the registration of the Products in the Territory (including applications for registration), the Distributor's promotion and marketing activities and sales report, setting forth the quantity purchased of each of the Products, its updated inventory for the quantities of the Product, the sale price in the Territory and total sales per each Product (in units and values) including the number of patients treated with Glassia in the Territory during the report period.

13. Indemnification

13.1. Each party (referred to hereunder as the "**Indemnifying Party**") shall indemnify and hold harmless the other party and its directors, officers, agents, employees and representatives (the "**Beneficiaries**") from and against any and all claims, demands, actions, damages, liabilities, losses and reasonable expenses, including reasonable attorney's fees, arising out of the breach of this Agreement by the Indemnifying Party.

Notwithstanding the foregoing, neither party shall incur any liability in connection with, or be obliged to indemnify the other party for, any indirect, incidental and consequential damages and losses, including, without limitation, loss of income and/or profit.

13.2. As a condition precedent to each party's right (and its Beneficiaries' right) to be indemnified under this Agreement, the party claiming the right to be indemnified (the "**Indemnified Party**"): (i) shall promptly notify the Indemnifying Party of any relevant claims asserted or made, including any claims asserted or made by any governmental authority having jurisdiction; and (ii) shall include in such notice all information in its possession relating to the claim; and (iii) shall not negotiate or settle any such claim without the Indemnifying Party's prior written consent; and (iv) shall fully cooperate with the Indemnifying Party in the defense and settlement of such claim.

13.3. The Indemnifying Party shall have full control over the defense and the right to settle any such claim on such terms it deems appropriate, provided that such settlement includes an unconditional release of the Indemnified Party and its respective Beneficiaries from all liability arising out of such claim and does not include a statement as to an admission of fault, culpability or failure to act by or on behalf of the Indemnified Party or any of its respective Beneficiaries.

13.4. The Indemnifying Party may conduct the defense against a claim by itself, if the Indemnifying Party fails to do so, and in such case the Indemnifying Party shall be entitled to an immediate reimbursement for all reasonable legal fees incurred by it in that connection.

14. Insurance

14.1. The Supplier shall purchase and maintain, at its own cost, a **Product Liability policy**, covering each occurrence of bodily injury due to a defective approved (licensed) Product in an amount of not less than [*****]US Dollars (US$[*****]) per event and in the aggregate per annum, by a reputable insurer. Such Product Liability policy shall:

14.1.1. include worldwide territorial and law and jurisdiction scope of coverage and shall be endorsed to specifically name the Distributor as an Additional Insured under and subject to the terms of its Vendors' (distributors') Extension, in the form of **Appendix F** hereto.

14.1.2. not be materially reduced or canceled without a prior written notification to be sent to the Distributor, by registered mail, sixty (60) days in advance;

14.1.3. be renewed by the Supplier for additional period of at least seven (7) years following termination or expiration of this Agreement, or, a Run-Off Policy (which includes the same terms of insurance as above) shall be purchased by the Supplier on its own cost and shall include inter-alia an Extended Discovery (Reporting) Period of seven (7) years, as from the termination or expiration date of this Agreement and a Retroactive Date not later than the commencement of operations by the respective insured party according to this Agreement, even if such operations began prior to the date of signature of this Agreement.

14.2. The Distributor shall purchase and maintain, at its own cost, a **Product Liability policy**, covering each occurrence of bodily injury or property damage due to any act of negligence, also while storage and handling the Products, in an amount of not less than [*****] US Dollars (US$[*****]) (or equivalent in EURO) per event and in aggregate per annum. Such insurance shall:

14.2.1. be endorsed to specifically name Kamada as an Additional Insured. Such insurance policy shall not be materially reduced or canceled without a prior written notification to be sent to the Supplier, by registered mail, sixty (60) days in advance;

14.2.2. be issued by a reputable insurer and shall include the Supplier as additional insured with respect to any liabilities which might be imposed on it as a result of the insured party's act or omission; only if based Claims Made, be renewed by the Distributor for additional period of at least seven (7) years following termination or expiration of this Agreement, or will include an extended discovery period of seven (7) years from the termination or expiration date of this Agreement and a retroactive date not later than the commencement of operations by the Distributor according to this Agreement, even if such operations began prior to the date of signature of this Agreement.

14.2.3. be subject to a worldwide law and jurisdiction.

14.3. Upon request, each of the parties shall provide the other party with a certificate of insurance in English, for each period of insurance, signed by the respective insurer, confirming the cover under the policy as set out above. The issuance of any such policy will not constitute an approval that the above insurance is in accordance with the provisions of this Agreement and will not impose any liability on either party; nor will it be considered as reducing either party's liability under this Agreement and under any applicable law.

15. <u>Trademarks/Patent Infringement</u>

15.1. The Distributor acknowledges the Supplier's exclusive right, title and interest in and to the Trademarks, whether registered in the Territory or not.

15.2. The Supplier hereby grants to the Distributor the non-assignable, non-transferable license to use and display the Trademarks, during the term of this Agreement, solely in connection with the promotion, sale and distribution of the Products in the Territory under the terms of this Agreement.

15.3. The Distributor shall not use and/or register, nor have registered, any trademarks, trade names or symbols which are identical to the Trademarks or to other trade names or symbols used by the Supplier, or which are confusingly similar thereto, in the Territory or elsewhere.

15.4. All rights arising from the use of the Trademarks in the Territory shall inure solely to the Supplier's benefit. Nothing contained herein shall give the Distributor any right, title or interest in the Trademarks and/or other trade names or symbols of the Supplier, nor in any contraction, variation or abbreviation of any of them.

15.5. Following expiration or termination hereof with respect to each country within the Territory, if applicable, the Distributor will be precluded from using the Trademarks in any way, and shall immediately destroy or return to the Supplier any material containing any of the Trademarks, which pertains or is intended for use in each such country.

15.6. The Distributor shall notify the Supplier of any infringement in the Territory of any of the Trademarks or other trade names or symbols related to the Supplier and/or the Products that comes to the Distributor's attention, and shall cooperate with the Supplier, as reasonably required, in order to stop such infringement.

15.7. The Distributor shall notify the Supplier in writing, immediately upon its receiving or being notified of any suit or claim based on an alleged infringement of a patent, or other proprietary right of any third party, by the Distributor and/or the Supplier, due to the importation, marketing, distribution or sale of any of the Products in the Territory. The Distributor shall permit the Supplier, at the Supplier's sole discretion and at the Supplier's own cost, to handle and control such claim or suit.

15.8. In the event that the Distributor is precluded from using the Trademarks in any country within the Territory during the term of this Agreement, the Supplier may register other trademarks with respect to the Products in such country, and the provisions of this Section 15 shall apply *mutatis mutandis* to such other trademarks.

16. Pharmacovigilance

Without derogating from the generality of Section 3.9 above:

16.1. The Supplier shall be responsible for establishing a pharmacovigilance monitoring system, with the reasonable assistance of the Distributor. Such monitoring system will include (i) provision of minimum pharmacovigilance information regarding a reporter who is identifiable by name, initials and/or address; (ii) an identifiable patient/subject (i.e., identifiable by patient number, date of birth, age, or gender); (iii) at least one suspected substance/medicinal product; and (iv) at least one suspected adverse drug event.

16.2. The Distributor shall provide all necessary assistance to the Supplier in the establishment and maintaining the pharmacovigilance monitoring system as the distributor of the Products in the Territory; such assistance shall include field corrections, product withdrawals, adverse event reporting and complaint reporting to the Supplier or any other relevant report or action required under any applicable law.

16.3. Without derogating from the above, the parties shall abide by the terms of the Safety Data Exchange Agreement attached hereto as **Appendix G**.

16.4. Each party shall immediately notify the other party of any information it receives regarding any threatened or pending action, inspection or communication by or from any party, including, without limitation, a regulatory authority which may affect the safety or efficacy claims of the Product or the continued marketing of the Product. Upon receipt of such information, the parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

16.5 The Distributor shall have responsibility for investigating any complaint in the Territory, with cooperation and assistance from the Supplier, and shall inform the Supplier of any information discovered in the course of the investigation that could show that the complaint is justified and that it resulted from the Supplier's actions or omissions.

17. Term & Termination

17.1. Unless earlier terminated pursuant to any of the provisions of this Agreement, this Agreement shall commence on the Effective Date and continue in full force and effect for a period of five (5) years.

17.2. This Agreement shall be automatically renewed for additional successive periods of one (1) year each (the "**Additional Periods**"), unless either party notifies the other party in writing of its desire to terminate this Agreement by a prior written notice of at least twelve (12) months before the expiry of any of the Additional Periods.

17.3. Each party may terminate this Agreement with immediate effect in case of a material breach of this Agreement by the other party, by giving a notice in writing specifying the breach.

It is agreed that a breach of any provision under the following Sections shall be considered as a material breach of this Agreement: 2.2, 3.3, 3.6, 3.12, , 4.5, , 4.10, 4.11, 6, 11, 13.1, 15.3, 15.5, 15.7, 16, , 18.2, 19, 20, 21.3, 24.1 and 25. Moreover, any breach of any other provision of this Agreement shall be considered a material breach if such breach is not remedied within thirty (30) days following a request in writing by the other party demanding compliance with the terms of such provision.

17.4. In addition, either party may immediately terminate this Agreement if the other party is declared bankrupt or insolvent, or request or suffer the appointment of a receiver for its assets, or make a composition with its creditors, or take or suffer any similar action in consequence of debt, and the order or act as aforesaid is not cancelled within sixty (60) days of the grant of such order or the performance of such act.

17.5. In addition, the Supplier may terminate this Agreement with respect to all countries of the Territory or with respect to certain countries only, with immediate effect in any of the following events:

17.5.1. change of control of the Distributor;

17.5.2. failure of the Distributor to register the Products in the Territory and obtain all the approvals required for their marketing and sale within the Territory within the period set forth in Section 4.8 above as a consequence of its own omission;

17.5.3. failure of the Distributor to purchase and pay for the Minimum Quantity pursuant to Section 8 during two (2) consecutive years, , provided that the Distributor will be obligated, during the second marketing year, to purchase Minimum Quantity also for the preceding marketing year on a Product by Product basis; or

17.5.4. Distributor discontinues selling the Products for any reason, after completing the registration and obtaining the required approvals, for longer than 45 (forty five) days, or 90 (ninety) days or more in the event that such discontinuation is caused due to a force majeure as prescribed in Section 22 below.

17.6. The Distributor shall not be entitled to any indemnification or compensation of any kind, including without limitation in connection with goodwill or loss of good will, nor for any reimbursement for any expenditures incurred by it or any investments made by it with respect to this Agreement, upon, or by reason of, the expiration or termination of this Agreement by the Supplier for any reason, except in case of termination with cause by Distributor due to Supplier's breach of this Agreement.

18. Effects of Termination

18.1. The Distributor undertakes that commencing at least three (3) months prior to expiration of this Agreement, or immediately following a notice of termination, as the case may be, but without derogating from the Supplier's rights under Section 4.7 above, it shall, without delay, fully cooperate with the Supplier or any designee thereof, take all steps required to provide the Supplier with relevant information, including without limitation detailed customers and sub-distributors lists, sign and vest all documents, to enable the continued uninterrupted distribution and sale of the Products in the Territory by or through the Supplier, an affiliate or a designee thereof.

18.2. Upon expiry or termination of this Agreement, the Distributor shall return to the Supplier all promotional material and other documents (and all copies thereof) and samples, which have been supplied to it by the Supplier and are in the Distributor's possession, or under its control.

18.3. Within thirty (30) days following the expiration or termination of this Agreement, the Supplier, at its sole option, may purchase from the Distributor any or all quantities of the Products, which the Distributor then has in stock, provided that they are still in good condition and in original packing and that they are not expired, at the lower between the purchase price originally paid by the Distributor to the Supplier for such Products including duties and freight costs incurred for importation, if applicable. The Distributor may sell in the Territory on a non-exclusive basis any Products not so purchased by the Supplier, subject to the terms of this Agreement, within a period of six (6) months following such expiration or termination, but no later than one hundred and twenty (120) days prior to the Products' expiry date. Products which are not repurchased by the Supplier nor sold by the Distributor pursuant to this Section 18.3 shall be destroyed by the Distributor, unless otherwise instructed in writing by the Supplier. Costs of destruction shall be shared equally by both parties.

19. Confidentiality

19.1. Distributor shall not, directly or indirectly, use or disclose to any third party all or any part of the Confidential Information heretofore or hereto after disclosed by or obtained from the Supplier except to the extent reasonably required for the performance of its obligations under this Agreement. The foregoing shall not apply to any Confidential Information which the Distributor can show by written records that:

19.1.1. at the time of its disclosure or thereafter is generally available to and known to the public, other than as a result of a disclosure by the Distributor or its representatives in breach of this Agreement;

19.1.2. was or becomes available to the Distributor, on a non-confidential basis from a third party source independent of any restrictions imposed by the Supplier;

19.1.3. has been independently acquired or developed by the Distributor without breaching this Agreement; or

19.1.4. has been lawfully in the possession of the Distributor prior to disclosure by the Supplier.

"**Confidential Information**" means, in this Agreement, any information or materials in oral, written, pictorial, magnetic, graphic or maintained or transferred in any other media, which have been previously disclosed or may hereafter be disclosed by the Supplier to the Distributor, relating to the financial, technological and business information, products, services and/or operations of the Supplier, including, but not limited to, business plans, agreements, trade secrets, know-how, patents, formulae, data, source code, object code, product plans, product specifications, technical information, customer lists, and all other information of any kind or nature whatsoever, whether or not contained or incorporated in drawings, photographs, memoranda, operational documents, models, prototypes, designs, quality control and test charts, lists, manuals and methods, whether or not labeled as confidential or proprietary, and including, without limitation, all copies, excerpts, modifications, translations, enhancements and adaptations of all the foregoing, whether made by the Distributor or otherwise.

19.2. In the event that the Distributor shall be legally required (by formal questioning or, in the written opinion of its legal counsel, by applicable securities laws) to disclose any Confidential Information of the Supplier, it shall immediately notify the Supplier in writing of such request or requirement prior to disclosure, so that the Supplier may seek an appropriate protective order with the reasonable assistance of the Distributor. If such order is not timely obtained, only such portion of the Confidential Information as specifically required shall be disclosed.

19.3. Distributor shall treat the Confidential Information with the same care as it would exercise in this handling of its own confidential or proprietary information and shall disclose such information on a need-to-know basis only to any of its employees, consultants and/ or contractors, provided that such individual is bound by confidentiality undertakings no less restrictive than the terms of this Section 19.

19.4. Upon written request by the Supplier, Distributor shall promptly return or securely destroy all tangible information (including, without limitation, drawings, specifications, data or samples), which contain or embody any Confidential Information, along with any and all copies thereof.

19.5. The Distributor's undertakings under this Section 19 shall survive the expiration or termination of this Agreement.

20. Non-Competition

Without the prior written consent of the Supplier, the Distributor shall not, directly or indirectly, whether as principal, partner, or as agent together with, or for any person, manufacture, use, test, sell, promote, market, distribute or sell in the Territory, or otherwise deal in any product, which is similar to and/or competes with any of the Products, during the term of this Agreement and for a twelve(12) months period thereafter, except this Agreement is terminated with cause by Distributor due to Supplier's breach of this Agreement.

21. Independent Contractors

21.1. The relationship between the Distributor and the Supplier under this Agreement is intended to be that of independent contractors, and, in connection with the marketing, distribution and sale of the Products: that of distributor and manufacturer (or supplier), and nothing contained herein shall constitute the Distributor, or any of the Distributor's employees or representatives, the agent or employee or representative of the Supplier for any purpose whatsoever.

21.2. Accordingly, the Distributor will have no power to act for or to bind the Supplier in any dealing with third parties, unless specifically authorized in advance and in writing by the Supplier.

21.3. The Distributor will indemnify the Supplier against any expenses, losses or damages, including legal expenses, caused to the Supplier as a result of or in connection with any claim or demand stemming from or related to the existence or the alleged existence of employment or agency relationship between the Distributor or any of his employees or representatives and the Supplier or any of its employees or representatives.

22. Force Majeure

22.1. Neither party shall in any event be held liable with respect to the other party or to others for losses or damages caused by non-performance, or a delay in the performance, of their obligations under this Agreement (except that of payment) to the extent that the same resulted from circumstances amounting to force majeure, including, inter alia, strikes, embargoes, riots, fires, floods, war, terror attacks, hurricanes, windstorms, acts or defaults of common carriers, shortage of materials, acts of God and acts of the state or of public authorities, or other causes beyond the reasonable control of the party affected thereby.

22.2. Each party hereto agrees to promptly notify the other party in writing of any event of force majeure under this Section and to employ all reasonable efforts toward prompt resumption of its performance hereunder when possible if such performance is delayed or interrupted by reason of such event. Financial inability to pay shall not be deemed a condition that is beyond a party's control.

23. Governing Law and Jurisdiction

23.1. This Agreement shall be governed by, and construed in accordance with, the laws of England and Wales, notwithstanding any contrary choice of law provisions. Any dispute, controversy or claim arising out of, or in relation to, this Agreement, including the validity, invalidity, breach, or termination thereof, shall be resolved by the competent courts in London, England.

23.2. The Distributor acknowledges and agrees that if it fails to perform certain obligations under this Agreement, including Sections 2.2, 15.3, 15.5, 19 and 20 it will cause immediate and irreparable harm and injury to the Supplier, for which monetary damages would not be adequate remedy. Therefore the Distributor agrees that, in addition to other remedies provided herein, the Supplier shall be entitled to an injunction restraining any violation or threatened violation by the Distributor of the provisions of the aforementioned Sections or to a specific performance or other equitable relief to enforce such provisions and, in connection therewith, that the Supplier shall not be obligated to post a bond for or otherwise ensure payment of any damages that might be incurred by the Distributor because of such legal action. Should any such legal action be brought by the Supplier, the Distributor shall not allege, and hereby waives, the defense that an adequate remedy exist without resorting to such legal action.

24. Assignment

24.1. Neither party shall assign its rights or obligations hereunder, in whole or in part without the prior written consent of the other party.

24.2. Notwithstanding the above, the Supplier may assign its rights and obligations hereunder, in whole or in part, to an affiliate thereof and to any succeeding entity.

25. Compliance with Anti-corruption Laws; Business Ethics; Privacy Laws

25.1. Each Party shall comply, and shall ensure that its officers, directors, employees, agents and any person or entity acting on its behalf or under its control (including its affiliates) comply, with all applicable anti-corruption laws and shall not engage in any illegal or unethical practices in connection with the activities to be performed under this Agreement and for commercialization of the Product.

25.2. No payments or transfers of value shall be made which have the purpose or effect of public or commercial bribery, acceptance or acquiescence in extortion, kickbacks or other unlawful or improper means of obtaining or retaining business or directing business to any person or entity. Distributor or any of its officers, directors, employees, agents and any person or entity acting on its behalf or under its control (including its affiliates) shall not, directly or indirectly, offer, give, promise to give or authorize the giving of any money or other thing of value to induce any person to do, or to omit from doing, any act in violation of his or her lawful duty, to obtain any improper advantage, or to induce any person to use his or her influence improperly to affect or influence any act or decision.

25.3. None of the owners, directors, officers, employees of Distributor or its affiliates holds an official position, or has any duties including any consulting, ceremonial or titular position, or any employment relationship, with any country government, government department, agency or instrumentality (including any government-owned or government-controlled enterprise or government-owned hospital or other healthcare provider), or any outside consultancy group engaged thereby, or any public international organization or political party, or are candidates for political office in any countries.

25.4. Distributor understands that Supplier places great value on its reputation as an ethical company and its commitment to comply with all applicable laws. Distributor acknowledges that Supplier has adopted a Code of Ethics (hereafter: "**Code of Ethics**"), in order to avoid incurring the liabilities entailed as consequence of the commission of the crimes provided by the aforesaid decree and to prevent the application of the relevant sanctions. The Code of Ethics is available at the following website: http://www.kamada.com/corporate-governance.php

25.5. Distributor further acknowledges, also on behalf of its affiliates, officers, directors, employees, contractors, sub-contractors and agents, the content and provisions of the Code of Ethics and undertakes to act (and to procure that its affiliate, officers, directors, employees, contractors, sub-contractors and agents act) in conformity with the provisions of such Code of Ethics. Failure by Distributor (and its affiliates, officers, directors, employees, contractors, sub-contractors and agents) to comply with the above mentioned provisions shall represent a material breach of this Agreement and therefore Supplier shall have the right to terminate the Agreement.

25.6. Distributor is responsible for executing an adequate preliminary due diligence on its affiliates, officers, directors, employees, contractors and agents, who will be involved for whatever purpose in the marketing and/or commercialization activities under this Agreement in order to check their expertise, skills, potential conflicts of interest and reputational background. Should the Supplier authorize the Distributor to sub-contract some of the above-mentioned marketing activities and/or to appoint one or more sub-distributors in the Territory, in addition to other specific requirements indicated by Supplier as a condition to its authorization, Distributor already undertakes to carry out an adequate preliminary due diligence on those sub-contractors and sub-distributors.

25.7. Distributor shall cooperate with Supplier in order to prevent any infringement of any applicable laws, including without limitation, anti-corruption laws and the Code of Ethics and to provide Supplier with any relevant information that the relevant national or international authorities, including any regulatory authority, may request. Distributor also undertakes to promptly provide Supplier with any request of information, access or inspection by any competent authority concerning Supplier and the Products.

25.8. It is understood that should Supplier be aware of any acts, facts, situations and omissions in breach of the provisions under this Agreement (even in consequence of the abovementioned controls and inspections) the liability of Distributor in relation to these facts, acts, situations and omissions is not excluded. The above listed duties and obligations of Distributor shall survive the termination of this Agreement and shall be effective in relation to the activities of Distributor concerning the operations contemplated in this Agreement until the actual conclusion of the same.

25.9. The Distributor, its personnel and its subcontractors shall comply with all applicable U.S. and international laws, regulations, and guidelines relating to protection of personal information, including the European Commission Directive 95/46, the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) under the Health Insurance Portability, General Data Protection Regulation (GDPR), and Accountability Act of 1996 (HIPAA), if applicable.

26. Miscellaneous

26.1. Except as expressly set forth in this Agreement, no right or license is granted by the Supplier to the Distributor under any patents, trade secrets, know-how, trademarks or other intellectual property rights owned by or licensed to the Supplier as of the Effective Date or at any time prior to during or after the term of this Agreement.

26.2. Entire Agreement. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and, except for the NDA, there have been no oral or other agreements of any kind whatsoever as a condition precedent or inducement to the signing of this Agreement or otherwise concerning this Agreement or the subject matter hereof.

26.3. This Agreement shall become effective only by signature of this Agreement by both Parties. If both Parties have not signed this Agreement, then this Agreement is not valid.

26.4. Waivers and Further Agreements. Any waiver of any terms or conditions of this Agreement shall not operate as a waiver of any other breach of such terms or conditions or any other term or condition, nor shall any failure to enforce any provision hereof operate as a waiver of such provision or of any other provision hereof; provided, however, that no such written waiver, unless it, by its own terms, explicitly provides to the contrary, shall be construed to effect a continuing waiver of the provision being waived and no such waiver in any instance shall constitute a waiver in any other instance or for any other purpose or impair the right of the party against whom such waiver is claimed in all other instances or for all other purposes to require full compliance with such provision. Each of the parties agrees to execute all such further instruments and documents and to take all such further action as the other party may reasonably require in order to effectuate the terms and purposes of this Agreement.

26.5. Amendments. This Agreement may not be amended, nor shall any waiver, change, modification, consent or discharge be effected except by an instrument in writing executed by both parties.

26.6. Severability. If any provision of this Agreement shall be held or deemed to be, or shall in fact be, invalid, inoperative or unenforceable as applied to any particular case in any jurisdiction or jurisdictions, or in all jurisdictions or in all cases, because of the conflict of any provision with any constitution or statute or rule of public policy or for any other reason, such circumstance shall not have the effect of rendering the provision or provisions in question invalid, inoperative or unenforceable in any other jurisdiction or in any other case or circumstance or of rendering any other provision or provisions herein contained invalid, inoperative or unenforceable to the extent that such other provisions are not themselves actually in conflict with such constitution, statute or rule of public policy, but this Agreement shall be reformed and construed in any such jurisdiction or case as if such invalid, inoperative or unenforceable provision had never been contained herein and such provision reformed so that it would be valid, operative and enforceable to the maximum extent permitted in such jurisdiction or in such case.

26.7. Section Headings. The headings contained in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

26.8. Notices. All notices and other communications required or desired to be given or sent by either party to the other shall be in writing, and shall be deemed to have been received the next business day after being successfully transmitted by fax as established by a transmission report, or after 10 (ten) days from being mailed by registered airmail; or at the time of delivery when manually delivered to the respective addresses set forth below:

to Supplier:	**to Distributor:**
Kamada Ltd.	TUTEUR S.A.C.I.F.I.A
2 Holzman Street, Weizmann Science Park, Rehovot 7670402, Israel	Encarnación Ezcurra 365 third floor, 1107 Buenos Aires , Argentina
Tel: 972-8-9406472 Fax: 972-8-9406473 Email: Amirl@kamada.com Attn.: Amir London, CEO	Tel: 54-11-5787-2222 Fax: 54-11-5787-2222 Email: apb@tuteur.com.ar Attn: Alberto Pablo Barros, Attorney

or to such other addresses as may be designated by notice, provided, however, that any notice of change of address shall be effective only upon receipt.

Without derogating from the above, notices regarding a breach of this Agreement or termination thereof, if successfully transmitted by facsimile as stipulated above, will be simultaneously delivered by registered mail or by courier, and shall be deemed to have been received on the next business day after successful facsimile transmission.

[Signature page follows]

IN WITNESS WHEREOF, the parties, each by its duly authorized signatory, have caused this Agreement to be executed as of the date first above-mentioned:

Kamada Ltd.

By: _____
Name: Amir London
Title: Chief Executive Officer

By: _____
Name: Chaime Orlev
Title: Chief Financial Officer

TUTEUR S.A.C.I.F.I.A

By: _____
Name: Jonathan Hahn
Title: President

Appendix A - The Products, Trademarks, Presentations, Indications and Prices

Product	Trademarks	Indications
AAT IV	“”, “GLASSIA”; Product Logos.	AATD
Anti D (IV + IM)	KamRho (D) IM KamRho (D) IV	IM - Prophylaxis of hemolytic disease of newborns IV- Treatment of immune thrombocytopenic purpura

Product	Minimum Supply Price; Transfer Price – Argentina Bolivia and Paraguay	Minimum Supply Price; Transfer Price – Uruguay
AAT IV per 50ml/ 1 gram vial	**Argentina** 2020 Minimum Supply Price - First [*****] supplied vials at US$[*****]/vial; and For any additional quantity US$[*****]/vial Transfer Price - The higher of 50% of the Product’s Net Price as sold by Tuteur in Argentina or Minimum Supply Price. 2021 Minimum Supply Price - First [*****] supplied vials at US$[*****]/vial; and For any additional quantity [*****]/vial Transfer Price - The higher of 50% of the Product’s Net Price as sold by Tuteur in Argentina or Minimum Supply Price. **Bolivia and Paraguay** Minimum Supply Price - will be agreed following registration of the Product. Transfer Price - The higher of 50% of the Product’s Net Price as sold by Tuteur in Argentina or Minimum Supply Price	2020 Minimum Supply Price - US$[*****]. Transfer Price - The higher of 50% of the Product’s Net Price as sold by Tuteur in Uruguay or Minimum Supply Price as specified above.
Anti D IM 2ml	**Argentina & Paraguay** 2020 Minimum Supply Price US$[*****] per 2ml Transfer Price - The higher of 50% of the Product’s Net Price as sold by Tuteur in Argentina or Minimum Supply Price. **Bolivia** Will be agreed prior to registration.	Minimum Supply Price - US$[*****]. Transfer Price - The higher of 50% of the Product’s Net Price as sold by Tuteur in Uruguay or Minimum Supply Price as specified above.
Anti D IM 0.85ml	N/A	Minimum Supply Price - US$[*****]. Transfer Price - The higher of 50% of the Product’s Net Price as sold by Tuteur in Uruguay or Minimum Supply Price as specified above.

Appendix B – Territory

Argentina, Paraguay, Bolivia and Uruguay

Appendix C – Minimum Vials per Shipment

Glassia - [*****] vials
KamRho (D) IM / IV- [*****] vials

Appendix D– Minimum Quantity

Year	Minimum Number of Glassia Vials per Marketing Year	
	Argentina	**Uruguay**
Year 1 - 2020	[*****]	[*****]
Year 2 - 2021	[*****]	[*****]
Year 3 and onwards	[*****]	[*****]

KamRho (D) IM 2ml / Argentina - [*****]
KamRho (D) IM 2ml / Paraguay - [*****]

Appendix E– Product Specifications

In accordance with the approved dossier in the Territory

Appendix F - Product Liability Insurance Side Letter

Date: _____

To: TUTEUR S.A.C.I.F.I.A S.A.

Re: Kamada Ltd. (the "Company") - Product Liability Insurance

Dear Sirs,

We are writing to inform you that we intend to include you as "Additional Insured" within the Company's Product Liability Insurance Policy (the "**Policy**").

Such inclusion is subject to the terms and conditions of the Policy, a copy of the relevant provisions is attached.

The inclusion is done at the Company's sole discretion and the Company may elect to cancel such inclusion, change or reduce the coverage at any time and for any reason whatsoever with or without notice.

Your inclusion in the Company's Product Liability Insurance is in addition to, and not instead of, any other insurance you have or are required to have under your agreement with your insurance companies.

Accordingly, nothing herein derogates, limits or relieves you from any of your responsibilities and liabilities under the Distribution Agreement with the Company, including, without limitations, the obligation to obtain the appropriate insurance coverage for your activities in connection with the Distribution Agreement.

Sincerely yours,

KAMADA LTD.

****

GENERAL PROVISIONS

Coverage is provided only for sales of the Company's Product in the ordinary course of vendor's (Distributor's) business.

Coverage is subject to vendor's written notice to the Company of any product liability claim immediately upon becoming aware of such claim or of circumstances that may lead to such claim.

Coverage expressly excludes liability for or deriving of any express or implied warranty, or any liability for distribution or sale for a purpose unauthorized by Kamada.

Coverage does not apply to injury or damage:

1. Arising out of any act of the vendor which changes the condition of the Product.

2. Arising out of any failure to maintain the Product in merchantable condition.

3. Arising out of alteration, treatment, processing, assembling, installation, repairing, packing/repacking, labeling, servicing and the like of such goods by the above vendor or retailer.

4. Occurring within the vendor's premises or occurring prior to sale of the designated Products.

The vendor undertakes to comply with the Policy's conditions in so far as applicable.

Any disputes that may arise between Vendor and Kamada and/or the Insurers regarding Policy conditions will be governed by Israeli Law.

Appendix G - Safety Data Exchange Agreement

[to be attached]

Appendix H – Release Letter

[on Distributor's letterhead]

TO WHOEVER IS CONCERNED

POWER OF ATTORNEY FOR TRANSFER OF REGISTRATION AND MARKETING AUTHORIZATIONS

Made this ___ day of _____.

Dear Sirs,

We hereby acknowledge that the Registration and Marketing Authorizations relating to the following product(s):

AAT IV

Anti D (IV+IM)

which are held by TUTEUR S.A.C.I.F.I.A., according to the laws of Argentina/Paraguay/Bolivia, and authorizing the sale of the product(s) in such country, are and shall remain the exclusive property of Kamada Ltd., a an Israeli company having its offices at 2 Holzman St., Science Park, P.O Box 4081, Rehovot, Israel, or of its affiliates.

Upon request of Kamada Ltd., TUTEUR S.A.C.I.F.I.A has agreed to promptly cease any use of the said Registration and Marketing Authorizations and unconditionally assign all and every lawfully assignable official title, or certificate or equivalent document concerning the Registration and Marketing Authorizations, whether applied for or granted, to Kamada Ltd or to Kamada Ltd's affiliate or other Kamada Ltd's nominee.

For such purpose therefore, it is hereby expressly provided hereby that this document constitutes an irrevocable power of attorney granted by TUTEUR S.A.C.I.F.I.A for the exclusive benefit of Kamada Ltd. or any concerned affiliate, to act and perform all necessary proceedings to instruct the Argentinean/Paraguayan/Bolivian authorities to transfer said Registration and Marketing Authorization to Kamada Ltd. or to any company indicated by Kamada Ltd.

This power of attorney is sufficient to act as described above and shall be considered as such by all Argentinean/Paraguayan/Bolivian authorities.

Further TUTEUR S.A.C.I.F.I.A undertakes, whenever requested and necessary to do so by Kamada Ltd, to execute such documents and to do such acts as may be required or desirable in order to permit or facilitate the transfer of said Registration and Marketing Authorizations upon Kamada Ltd.'s instructions.

TUTEUR S.A.C.I.F.I.A hereby acknowledges that the present document may be used for the purpose of transferring the Marketing Authorizations and to evidence ownership rights of Kamada Ltd. including before a Court of law, in case of a legal dispute.

Sincerely yours,

_____

By: **[*Distributor's full name's representative*]**
Title: **[*Distributor's representative's position*]**

TO WHOEVER IS CONCERNED

POWER OF ATTORNEY FOR TRANSFER OF REGISTRATION AND MARKETING AUTHORIZATIONS

Made this ___ day of _____.

Dear Sirs,

We hereby acknowledge that the Registration and Marketing Authorizations relating to the following product(s):

AAT IV

Anti D (IV+IM)

which are held by TUTEUR S.A., according to the laws of Uruguay, and authorizing the sale of the product(s) in such country, are and shall remain the exclusive property of Kamada Ltd., a an Israeli company having its offices at 2 Holzman St., Science Park, P.O Box 4081, Rehovot, Israel, or of its affiliates.

Upon request of Kamada Ltd., TUTEUR S.A has agreed to promptly cease any use of the said Registration and Marketing Authorizations and unconditionally assign all and every lawfully assignable official title, or certificate or equivalent document concerning the Registration and Marketing Authorizations, whether applied for or granted, to Kamada Ltd or to Kamada Ltd‘s affiliate or other Kamada Ltd‘s nominee.

For such purpose therefore, it is hereby expressly provided hereby that this document constitutes an irrevocable power of attorney granted by TUTEUR S.A for the exclusive benefit of Kamada Ltd. or any concerned affiliate, to act and perform all necessary proceedings to instruct the Uruguayan authorities to transfer said Registration and Marketing Authorization to Kamada Ltd. or to any company indicated by Kamada Ltd.

This power of attorney is sufficient to act as described above and shall be considered as such by all Uruguayan authorities.

Further TUTEUR S.A undertakes, whenever requested and necessary to do so by Kamada Ltd, to execute such documents and to do such acts as may be required or desirable in order to permit or facilitate the transfer of said Registration and Marketing Authorizations upon Kamada Ltd.’s instructions.

TUTEUR S.A hereby acknowledges that the present document may be used for the purpose of transferring the Marketing Authorizations and to evidence ownership rights of Kamada Ltd. including before a Court of law, in case of a legal dispute.

Sincerely yours,

_____

By: **[*Distributor’s full name’s representative*]**
Title: **[*Distributor’s representative’s position*]**

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.
[*****] indicates the redacted confidential portions of this exhibit.

BINDING TERM SHEET

Co-Development, Manufacturing, Supply and Distribution Agreement

April 27 2020

RECITALS	This Binding Term Sheet ("**Term Sheet**") summarizes the main terms and conditions under which Kamada Ltd., of 2 Holzman St. Science Park, P.O. Box 4801, Rehovot, 7670402, Israel ("**KAMADA**") and Kedrion S.p.A, of Castelvecchio Pascoli, Località Ai Conti, 55051 Barga (LU), Italy ("**KEDRION**") will enter into a long-term agreement for the co-development, manufacturing, supply and distribution of the Product (as defined below) (Each of KAMADA and KEDRION is referred to hereunder as a "**Party**" and together the "**Parties**"). By signing this Term Sheet, the Parties agree to be legally bound by the provisions set forth below, and each Party shall be legally bound to proceed to negotiate and execute a definitive agreement or agreements for the co-development, manufacturing, supply of Source Plasma (as defined below) and Product (as defined below), distribution and quality as may be required, and any other related agreements (collectively, the "**Definitive Agreements**" and individually, a "**Definitive Agreement**"). In addition to the terms and conditions provided in this Term-Sheet, each of the Definitive Agreements shall contain representations, warranties, covenants, indemnification obligations, insurance commitments, limitation of liability and other provisions that are customary for these agreements. The Parties shall make all commercial reasonable best efforts to execute the required Definitive Agreements within one hundred and twenty (120) days following the execution of this Term Sheet. The execution of any of the Definitive Agreements, is subject to obtaining the approval of the Parties' senior management and Board of Directors.
PRODUCT	Anti-SARS-COV-2 (and its derivatives) Immunoglobulins derived from hyper-immune plasma sourced from COVID-19 convalescent patients or vaccinated donors (the "**COVID Source Plasma**"), administrated by Intravenous therapy (IV) or Intramuscular injection (IM) and all its improvements or enhancements (the "**Product**")
TERRITORY	Worldwide
DISTRIBUTION RIGHTS	i. KEDRION will retain the distribution rights of the Product in the territories listed in **Exhibit A** ("**KEDRION Territory**") ii. KAMADA will retain the distribution rights of the Product in all territories not included in the KEDRION Territory and excluding China ("**KAMADA Territory**") KAMADA recognizes that it may be worthwhile to engage KEDRION, or any of its subsidiary entities, to be its sole distributer in selected countries included in the KAMADA Territory, including, but not limited to, Turkey, India, Mexico, Colombia, Switzerland and Brazil, provided that the Parties, negotiating in good faith, will agree on amicable commercial engagement in each such specific country. iii. It is hereby agreed between the parties, that distribution rights for the territory of China shall be co-shared between the parties. It is further agreed that the terms and conditions with respect to development, manufacturing, registration, distribution and sale in the territory of China will be negotiated between the parties in good faith and will be incorporated into a separate definitive agreement.

EXCLUSIVITY	i. KEDRION will be the sole and exclusive distributor of the Product in the KEDRION Territory and KAMADA shall be the sole and exclusive manufacturer of the Product in the Territory and the sole and exclusive distributor of the Product in the KAMADA Territory. ii. It is hereby agreed that KEDRION and KAMADA shall not develop, manufacture, distribute or sell (either directly or through any third parties) any other plasma derived Anti-SARS-COV-2 Immunoglobulins, sourced from convalescent patients, vaccinated donors or from any other source that may compete with the Product in the Territory. Provided however, that in the event KAMADA will be unable to supply, due to manufacturing capacity constraints, all the quantities of the Product as required by KEDRION for distribution in the KEDRION Territory, then KEDRION may develop, manufacture, register, distribute and sell a plasma derived Anti-SARS-COV-2 Immunoglobulins manufactured through Cohn fractionation **("KEDRION Manufactured Product**"). For the avoidance of doubt, it is hereby agreed that the KEDRION Manufactured Product may only be distributed by KEDRION to fulfill excess demand in the KEDRION Territory which exceeds KAMADA's supply of the Product in a given time period. The Parties agree to define in the Definitive Agreement the KAMADA anticipated manufacturing capacity and production plan, together with mechanism, terms and conditions with respect to such potential production by KEDRION. For the avoidance of any doubt KEDRION shall not distribute the KEDRION Manufactured Product in the KAMADA Territory.
TERM	The initial term of the Definitive Agreements will be for five (5) years, with a start date as of the date of execution of this Term-Sheet (the "**Effective Date**" and the "**Initial Term**"); provided however, that the Parties may mutually agree to extend the term of the Definitive Agreements for consecutive three (3) year renewal terms (each a "**Renewal Term**" and together with the Initial Term, the "**Term**"), by mutual agreement entered into at least six (6) months prior to the end of the Initial Term or the then current Renewal Term.
ACTIVITIES AND RESPONSIBILITIES	i. Process Development and Product Manufacturing – KAMADA will be responsible, at its sole costs and expense, for the process development activities and the manufacturing of the Product for all intended uses, including but not limited to research and development activities and commercial distribution and marketing in the Territory. ii. COVID Source Plasma – KEDRION shall be responsible for the collection and supply free of charge and at its own costs and expenses (other than as provided under the Financial Consideration section below), of all quantities of the COVID Source Plasma as may be required for: (i) distribution the Product by the Parties in the Territory; and (ii) for the Product process development activities, as well as for any activity, including, but not limited to, pre-clinical, clinical studies or post marketing commitments and any related studies that may be required for obtaining the Regulatory Approval (as defined below) in the Territory. The COVID Source Plasma will be collected from U.S. or EU convalescent patients or vaccinated donors. KEDRION shall be responsible for, and shall bear all costs and expenses associated with the procurement, release and delivery of the required quantities of the COVID Source Plasma, directly or through its Subsidiaries, and will make such quantities available at the location set by KAMADA DDP (Incoterms 2010). In the event that KAMADA's support is required for the procurement of COVID Source Plasma from any third party and/or with respect to shipment or delivery of the COVID Source Plasma, then KAMADA will be entitled for full reimbursement of its costs associated with such activities. COVID Source Plasma release testing and shipment will be carried-out in conformity to applicable standards and/or regulations by any relevant regulatory authorities including the US Food and Drug Administration (the "**FDA**").

iii. Raw Materials and Manufacturing Equipment – KAMADA will be responsible for sourcing, qualifying and if applicable the installation of all raw materials (other than the COVID Source Plasma) and manufacturing equipment necessary for production of the Product.

iv. Product Registration – KAMADA will be responsible for all activities necessary for obtaining Regulatory Approval (as defined below) for the Product in the Territory, excluding Italy, for which obtaining of any required Regulatory Approval will be the responsibility of KEDRION, which will be the owner of the Marketing Authorization in Italy.

"Regulatory Approval" shall mean, the registration, authorization, approvals (including but not limited to New Drug Applications (NDA), Biological License Applications (BLA), and any other similar approvals), licenses, supplements and amendments, pre and post approvals, of any national , supra-national, regional, state or local regulatory agencies or authorities, including but not limited to the FDA and EMA approvals, necessary for the development, manufacture, distribution, or sale of the Product in the Territory.

v. Regulatory Approval Costs – It is hereby agreed that any costs associated with the obtaining of Regulatory Approval in the KEDRION Territory, including but not limited to all the applicable regulatory fees (such as fees for regulatory meetings, applications and authorizations and renewals), as well as pre-clinical, clinical studies, post marketing commitments, consultancy, regulatory inspections will be shared [*****] between the Parties.

Regulatory approval costs required for obtaining Regulatory Approval in the KAMADA Territory will be under the responsibility and costs of KAMADA.

vi. Compassionate-Use/Named-Patient-Basis Approval and Reimbursement Approval – Each party will be responsible for all reimbursement activities and approvals, as well as all compassionate-use/named-patient-basis activities and approvals in its designated territories and shall bare all costs associated with such activities in its designated territories.

vii. Sales, Marketing, Medical Affairs and Pharmacovigilance Activities - Each party will be responsible for all sales, marketing, medical affairs and pharmacovigilance activities in its designated territories and shall bare all costs associated with such activities in its designated territories.

viii. Product Release – KAMADA will be responsible of all analytical, characterization and potency testing, including, if applicable, QP release required to release the Product for pre-clinical, clinical, post clinical or for commercial use. If applicable, KEDRION will provide KAMADA with QP services in the EU free of charge.

ix. Product Testing - KAMADA and KEDRION will collaborate and will [*****] share all costs associated with the development and validation of all required analytical, characterization and potency testing including titer determination, in vitro neutralization and biological activity testing as will be required

x. Supply Plan and Rolling Forecast – The Parties will negotiate in good faith and agree on a binding supply plan and rolling forecast to ensure continued supply of adequate quantities of COVID Source Plasma and Product.

The Parties acknowledge that during the initial months of the Term there will be limited supply of COVID Source Plasma as well as limited manufacturing capacity of the Product, as such, the Parties, through their Joint Steering Committee (as defined below) will agree on manufacturing and supply priorities. It is hereby agreed between the Parties that the initial priority will be to supply Product to the Italian and Israeli markets.

It is hereby agreed between the Parties that KAMADA retains the right to utilize up to twenty percent (20%) of all supplied quantities of COVID Source Plasma for manufacturing of Product for distribution in the KAMADA Territory (see Financial Consideration section below for details on the payment to be made by KAMADA on account of such quantities of COVID Source Plasma). The percentage set forth in this paragraph shall be negotiated in good faith on an annual basis taking into consideration the yearly forecast in the different territories.

xi. Product Delivery – Delivery of the Product by KAMADA to KEDRION will be made EXW (Incoterms 2020) KAMADA's manufacturing facility in Israel (i.e. KAMADA will be responsible for packing the Product and KEDRION will be responsible for the Product pick-up from KAMADA's manufacturing facility and shipment).

FINANCIAL CONSIDERATIONS	i. The sole payment payable by KEDRION to KAMADA for such quantities of the Product supplied to KEDRION by KAMADA for distribution in the KEDRION Territory shall be [*****] percent ([*****] %) of the average Net Price (as defined below) per ml sold by KEDRION in each country in the KEDRION Territory. "**Net Price**" means, for a specified calendar quarter, the revenue of KEDRION from sales of Product in each country in the KEDRION Territory to independent third party or other customers less: (a) discounts and rebates as actually given to such third party customers (b) VAT; (c) amounts actually repaid or credited by reason of rejection or return of any previously sold Product; and (d) any governmental charges imposed upon Product sales. The revenue records of KEDRION will be according to International Financial Reporting Standards (IFRS). ii. The financial consideration in the event that KAMADA engages KEDRION, or any of its subsidiaries, for the distribution of the Product in any country in the KAMADA Territory will be discussed and agreed on a case by case basis. iii. The sole payment payable by KAMADA to KEDRION for such quantities of the Product manufactured by KAMADA for development, manufacturing, clinical trials, registration and distribution in the KAMADA Territory shall be equal to [*****] US Dollars (US$ [*****]) per liter of COVID Source Plasma (the "**Source Plasma Transfer Price**") utilized by KAMADA for manufacturing of Product for distribution by KAMADA in the KAMADA Territory. The Parties acknowledge that the COVID Source Plasma Transfer Price may be different for COVID Source Plasma derived from convalescent patients and COVID Source Plasma derived from vaccinated donors. The Parties will negotiate in good faith a potential modification to the COVID Source Plasma Transfer Price in the event that: (i) the market price of COVID Source Plasma is higher by 15% or more of the Source Plasma Transfer Price; and/or (ii) sufficient quantities of COVID Source Plasma can be acquired by KAMADA from third parties at a price which represents a 15% or more discount over the Source Plasma Transfer Price. It is hereby agreed that, in the event that KEDRION will not be able to deliver sufficient quantities of COVID Source Plasma to support manufacturing by KAMADA of such required quantities of Product for distribution by KAMADA in the KAMADA Territory, then KAMADA retains the right to acquire any such required quantity of COVID Source Plasma from third parties. For the avoidance of doubt it is hereby clarified that no payment will be due to KEDRION from KAMADA in the event that the COVID Source Plasma utilized for manufacturing of the Product for distribution in the KAMADA Territory is sourced from third parties.

TOLL MANUFACTURING	i. KAMADA retains the right to enter into toll manufacturing arrangements directly or indirectly with any governmental or quasi-governmental agencies or institutions (such as national blood banks), ("**Agencies**"), in the KAMADA Territory, including but not limited to Israel, for the manufacturing and supply of the Product from COVID Source Plasma supplied by such Agencies or on their behalf. For the avoidance of doubt, it is hereby clarified that no payment of any kind or type will be due to KEDRION by KAMADA in the event that the COVID Source Plasma will be supplied by such Agencies or on their behalf to be utilized for manufacturing of the Product for distribution by KAMADA under such toll manufacturing arrangements. ii. KEDRION retains the right to enter into toll manufacturing arrangements directly or indirectly with any Agencies (as defined above), in the KEDRION Territory (excluding the United States), as well as certain countries in the KAMADA Territory for which KAMADA may be prohibited by law to operate in, for the manufacturing and supply of a KEDRION Manufactured Product from COVID Source Plasma supplied by such Agencies or on their behalf. For the avoidance of doubt, it is hereby clarified that in the event that the COVID Source Plasma will be supplied by such Agencies or on their behalf, such COVID Source Plasma will be utilized exclusively for manufacturing of such product for distribution by KEDRION under such toll manufacturing arrangements. iii. In the event that KEDRION enters into toll manufacturing agreements with the respective Agencies in KEDRION Territory, for the Product to be manufactured by KAMADA then the parties will negotiate in good faith the related financial consideration. To dispel doubt, such event does not involve technology transfer from KAMADA to KEDRION.
PAYMENT TERMS	Any payments under the Definitive Agreements shall be made forty-five (45) days after receipt of invoice. In the event the invoices are not paid on the due date, they bear an interest to be defined in the definitive agreements. All amounts payable by either Party under all the Definitive Agreements will be payable in U.S. Dollars
JOINT STEERING COMMITTEE	KAMADA and KEDRION will form a joint steering committee including equal representatives of each entity which will oversee all activities during the Term of this Term-Sheet and the Definitive Agreements ("**JSC**"). The JSC will meet as needed but not less than on a quarterly basis.
OWNERSHIP	Subject to KEDRION's distribution rights specified above, KAMADA shall own all proprietary rights in the Product and all improvements, enhancements or developments thereof, including all intellectual property rights (including trade marks), know-how, trade-secrets thereof and any forms of Regulatory Approvals with respect to the Product. For the avoidance of doubt it is clarified that KEDRION will own all rights related to the KEDRION Manufactured Product

CONFIDENTIALITY	The terms of the Mutual Confidentiality Agreement entered into between the Parties effective as of March 30, 2020 (the "**CDA**"), are incorporated herein by reference, and will apply to any and all discussions and Confidential Information (as defined in the CDA) exchanged by the Parties under this Term Sheet and/or any Definitive Agreements as contemplated herein, in any form, whether oral, written, electronic or otherwise. In addition, the "**Purpose**" as defined in the CDA shall be deemed to include discussions between the Parties with respect to the terms of this Term Sheet and the Definitive Agreements and with respect to the transactions contemplated herein. Without derogating from the foregoing, neither Party shall disclose or discuss the terms of this Term Sheet with any persons other than its representatives who have a "need to know" and who are bound by similar confidentiality and non-use obligations, without the prior written approval of the other Party. The confidentiality and non-use obligations of the Parties herein shall continue for the period/s set forth in the CDA. KEDRION acknowledges that KAMADA is a public company whose shares are publicly traded on the Tel-Aviv Stock Exchange and the NASDAQ. Accordingly: (a) KAMADA's confidential information, as well as this Term Sheet may be considered as "inside information" pursuant to Israeli and US securities laws and regulations and KEDRION undertakes not to use any confidential information in violation of the applicable securities laws; and (b) KAMADA may be required to make certain disclosures and publications under applicable laws, which may include this Term Sheet, the Definitive Agreements and related agreements. This provision shall survive the termination or expiration of this Term Sheet for any reason.
PUBLIC ANNOUNCEMENT	Notwithstanding the foregoing, if an announcement concerning this Term Sheet, and the Definitive Agreements is required by applicable law or any listing agreement with a national securities exchange or quotation system, the Party required to make such announcement may do so, provided that such Party shall provide notice to and a copy of such announcement as promptly as practicable in advance of such announcement and, to the extent practicable, take the views and comments of the other Party in respect of such announcement into account prior to making such announcement.
ASSIGNMENT	Neither Party shall assign or otherwise transfer this Term Sheet or any of its rights and obligations hereunder without the prior written consent of the other Party, which shall not be withheld or delayed unreasonably. Notwithstanding the foregoing, either Party shall not be restricted in any way from assigning this Term Sheet or any of the Definitive Agreements to any affiliate, or in connection with any sale or transfer of all or substantially all of the assets to which the Supply Agreement relates, or in connection with any change of control.
EXPENSES	Each Party shall bear its own expenses, including fees and expenses of legal, regulatory and financial advisors, in connection with the negotiation and execution of this Term Sheet and the Definitive Agreements.
TERM SHEET TERMINATION	This Term Sheet shall remain in full force and effect until the Definitive Agreements are executed by the Parties, or at the latest on June 30th 2021, unless early terminated by mutual agreement of the Parties.
GOVERNING LAW AND JURISDICTION; MISCELLANEOUS	This Term Sheet shall be governed by and construed in accordance with the laws of England and Wales, without regard to the conflicts of law principles thereof and the competent state or federal courts located in London, England shall have exclusive jurisdiction with respect to any disputes or actions arising from this Term Sheet. This Term Sheet may be executed in one or more counterparts, and by Parties in separate counterparts, each of which when so executed shall be deemed an original, but all of which together shall constitute one and the same instrument. This Term Sheet, to the extent signed and delivered by electronic means, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. Any amendments or modifications to this Term Sheet must be in writing and signed by duly authorized representatives of both of the Parties.

Signature page to follow

Executed by the Parties:

KEDRION S.P.A

By: _____
Name: Mr. Paolo Marcucci, CEO
Its: CEO
Date: April 27, 2020

KAMADA LTD

By: _____
Name: Amir London
Its: CEO
Date: April 27, 2020

By: _____
Name: Chaime Orlev
Its: CFO
Date: April 27', 2020

Exhibit A

KEDRION Territory: United States, all European Union ("EU") members, Australia, South Korea, United Kingdom, Switzerland and Norway.

Exhibit 4.35

ASSET PURCHASE AGREEMENT
BY
AND
BETWEEN
BLOOD AND PLASMA RESEARCH, INC.
AND
KAMADA PLASMA, LLC

Dated as of January 31, 2021

TABLE OF CONTENTS

List of Exhibits

ASSET INTEREST PURCHASE AGREEMENT

THIS ASSET INTEREST PURCHASE AGREEMENT (this "***Agreement***") is made and entered into as of January 31, 2021, by and between Blood and Plasma Research, Inc., a Texas corporation ("***Seller***"), and Kamada Plasma, LLC, a Delaware limited liability company ("***Buyer***").

WHEREAS, Seller is engaged in the collection, testing and processing of plasma and other blood products and using the resulting products thereof to sell specialty blood products and services to customers (the "***Business***"); and

WHEREAS, Seller desires to sell and assign to Buyer, and Buyer desires to purchase from Seller, substantially all the assets, and certain specified liabilities, of the Business, subject to the terms and conditions set forth herein; and

NOW, THEREFORE, for and in consideration of the premises, and the agreements, covenants, representations and warranties hereinafter set forth, and other good and valuable consideration, the receipt and adequacy all of which are acknowledged and confessed, the Parties agree as follows:

ARTICLE I
DEFINITIONS

Section 1.1 **Definitions.** Capitalized terms used in this Agreement have the following meanings:

"***Acquired Inventory***" has the meaning set forth in Section 2.1(a).

"***Acquisition Proposal***" has the meaning set forth in Section 6.4.

"***Affiliate***" means as to the Person in question, any Person that directly or indirectly controls, is controlled by, or is under common control with the Person in question; and the term "control" means possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person whether through ownership of voting securities, by contract or otherwise.

"***Affordable Care Act***" means, collectively, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010.

"***Agreement***" has the meaning set forth in the preamble to this Agreement.

"***Allocation Schedule***" has the meaning set forth in Section 2.7.

"***Assigned Contracts***" has the meaning set forth in Section 2.1(b).

"***Balance Sheet Date***" has the meaning set forth in Section 4.6(a).

"***Base Purchase Price***" has the meaning set forth in Section 2.5.

"***Basket Amount***" has the meaning set forth in Section 9.3(a)(i).

"***Benefit Plan***" means any plan, program, policy, practice, Contract or other arrangement providing for compensation, severance, bonus or incentive compensation, termination pay, deferred compensation, performance awards, stock or stock-related awards (including any stock purchase or stock option plan), equity-based awards, phantom equity, retention or change of control bonus, profit-sharing, severance, fringe, retirement, pension, death, medical, health, accident, life, vision or dental benefits, vacation, paid time off, disability, or other employee benefits or remuneration of any kind, whether written, unwritten or otherwise, funded or unfunded (including each "employee benefit plan" within the meaning of Section 3(3) of ERISA whether or not subject to ERISA) that is or has been maintained, sponsored, contributed to, or required to be contributed to, by Seller or its ERISA Affiliates for the benefit of any current or former employees, officers, directors, retirees, independent contractors or consultants or any of their respective spouses or dependents, or with respect to which Seller or any ERISA Affiliate has or may have any Liability, contingent or otherwise, in each case, including any such plan, program, policy, practice, Contract or other arrangement provided to an employee of Seller in connection with its relationship with PEO.

"***Books and Records***" has the meaning set forth in Section 2.1(l).

"***Business***" has the meaning set forth in the recitals to this Agreement.

"***Business Day***" means any day other than (i) a Saturday or a Sunday or (ii) a day on which banking and savings and loan institutions are authorized or required by law in the State of Texas to be closed.

"***Business Insurance Policies***" has the meaning set forth in Section 4.13.

"***Buyer***" has the meaning set forth in the preamble to this Agreement.

"***Buyer Fundamental Representations***" means the representations and warranties of Buyer set forth in Section 5.1 and Section 5.5.

"***Buyer Indemnified Party***" has the meaning set forth in Section 9.1.

"***CARES Act***" means the Coronavirus Aid, Relief, and Economic Security (CARES) Act (2020) and the related rules and regulations (including interim regulations and guidance) promulgated thereunder, whether before or after Closing.

"***CHOW***" has the meaning set forth in Section 8.5.

"***Claims***" has the meaning set forth in Section 9.5.

"***Closing***" has the meaning set forth in Section 3.1.

"***Closing Date***" has the meaning set forth in Section 3.1.

"***COBRA***" means the group health plan continuation of coverage requirements of Title I, Part 6, of ERISA and Section 4980B of the Code.

"***Code***" means the Internal Revenue Code of 1986 and the rules and regulations promulgated thereunder.

"***Competing Business***" has the meaning set forth in Section 8.2(a).

"***Consulting Agreement***" means the consulting agreement by and between Buyer and Kristi Lovelady dated as of the Closing Date, and which agreement is attached hereto as **Exhibit A**.

"***Contract***" means any written or oral contract, agreement, indenture, note, bond, mortgage, loan, instrument, lease, deed, license, commitment, undertaking or other legally binding arrangement or understanding.

"***Destruction Costs***" means the cost to properly dispose of Scrap Inventory.

"***Employees***" has the meaning set forth in Section 4.24(b).

"***Employment Agreements***" means the employment agreements by and between Buyer and Dan Browning and Jean Browning dated as of the Closing Date, and which agreements are attached hereto as **Exhibit B** and **Exhibit C**, respectively.

"***Encumbrances***" means any mortgage, deed of trust, lien, claim, pledge, security interest, right of first refusal, charge, right of way, easement, covenant, encroachment, option to purchase or lease or otherwise acquire any interest, conditional sale, encumbrance or any other security interest or rights of third parties or any Contract to create any of the foregoing, or other restriction of any kind or similar encumbrances.

"***Environmental Claim***" means any claim, action, cause of action or notice by any Person alleging potential Liability (including potential Liability for investigatory costs, cleanup costs, governmental response costs, natural resources damages, property damages, personal injuries, or penalties) arising out of, based on or resulting from the presence, or release or threat of release into the environment, of any Materials of Environmental Concern.

"***Environmental Laws***" means all Laws relating to Materials of Environmental Concern, public health or safety, pollution or protection of the environment (including ambient air, surface water, ground water, land surface or sub-surface strata), natural resources or endangered or threatened species, including, but not limited to, the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. § 9601 *et seq*., the Resource Conservation and Recovery Act, 42 U.S.C. § 6901 *et seq*., the Toxic Substances Control Act, 15 U.S.C. § 2601 *et seq*., the Clean Air Act, 42 U.S.C. § 7401 *et seq*., the Clean Water Act, 33 U.S.C. § 1251 *et seq*., and all similar state and local laws, regulations or other legal requirements promulgated under any of the foregoing such Laws.

"***ERISA***" means the Employee Retirement Income Security Act of 1974 and the rules and regulations promulgated thereunder.

"***ERISA Affiliate***" means any Person, entity, company, trade or business that is a member of a "controlled group of corporations," under "common control", an "affiliated service group" or would otherwise be considered a single employer with Seller under Section 414 of the Code or Section 4001(a)(14) of ERISA.

"***Excluded Assets***" has the meaning set forth in Section 2.2.

"***Excluded Contracts***" has the meaning set forth in Section 2.2(a).

"***FCPA***" has the meaning set forth in Section 4.17(b).

"***FDA***" means the U.S. Food and Drug Administration.

"***FDA Application Integrity Policy***" has the meaning set forth in Section 1.1(a).

"***Financial Statements***" has the meaning set forth in Section 4.6(a).

"***GAAP***" means generally accepted accounting principles in the United States of America.

"***Governmental Authority***" means any national, supra-national, state, municipal or local government or other political subdivision thereof, whether domestic or foreign, or any entity exercising executive, legislative, judicial, regulatory or administrative functions of government, including any governmental authority, bureau, agency, department, board, commission or instrumentality of the United States, any State of the United States or any political subdivision thereof, and any court, tribunal or arbitrator(s) of competent jurisdiction, and any stock exchange or self-regulatory organization or quasi-governmental entity to the extent that the rules, regulations or Orders of such organization or entity have the force of law.

"***Healthcare Laws***" means any Law relating to healthcare regulatory matters, including, but not limited to: the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Anti-Kickback Act of 1986, 41 U.S.C. §§ 51-58; the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301-399i; state and federal privacy laws, and all applicable implementing regulations, rules, ordinances, judgments, and Orders; and any similar state and local statutes, regulations, rules, ordinances, judgments, and Orders; and all applicable federal, state, and local licensing, certificate of need, regulatory and reimbursement, corporate practice of medicine, and physician fee splitting regulations, rules, ordinances, orders, and judgments applicable to healthcare service providers and/or plasma and blood centers providing the products and services that Seller provides.

"***Holdback Amount***" means USD $250,000.

"***Improper Payment Laws***" has the meaning set forth in Section 4.17(b).

"***Indebtedness***" means with respect to Seller, any direct or indirect indebtedness, Liabilities, or obligations of Seller: (i) for borrowed money; (ii) evidenced by any note, bond, debenture, debt security or other similar instruments; (iii) in respect of acceptance credit, letters of credit or similar facilities; (iv) under forward currency exchanges, interest rate protection agreements, swap agreements and hedging arrangements; (v) for the deferred purchase price of property, equipment or services (other than accounts payable in the ordinary course of business); (vi) created or arising under any conditional sale or other title retention agreement with respect to property acquired; (vii) under leases that are considered capital leases by Seller or would be considered capitalized leases under GAAP; (viii) secured by an Encumbrance on Seller's assets; (ix) owed to any Person under any noncompetition, severance or similar arrangement and Taxes thereon; (x) for escrow amounts, holdback amounts or earn-out payments in connection with acquisitions by Seller; (xi) for outstanding judgments or settlement amounts against or in respect of Seller; (xii) for change-of-control or similar payment or increased cost that is triggered in whole or in part by the transactions contemplated herein, and Taxes thereon; (xiii) under deferred compensation plans, phantom stock plans, severance or bonus plans, or similar arrangements made payable in whole or in part as a result of the transactions contemplated herein; (xiv) of the type referred to in the foregoing clauses of this definition of other Persons for which Seller is responsible or liable as guarantor; and (xv) for accrued and unpaid interest on, and any prepayment premiums, penalties, charges, assessments or similar fees and expenses in respect of, any of the foregoing obligations that are required to be paid by Seller in respect of any of the foregoing.

"***Indemnitee***" has the meaning set forth in Section 9.5(a).

"***Indemnitor***" has the meaning set forth in Section 9.5(a).

"***Independent Accounting Firm***" means Ernst & Young or such other independent accounting firm as may be approved by the mutual agreement of Buyer and Seller.

"***Intellectual Property Assets***" means all (i) copyrights, trademarks, trade names, brands, service marks, trade dress, logos, packaging designs, slogans, domain names, trade secrets, know-how, confidential or proprietary information, patents, inventions, discoveries or other intellectual property and proprietary rights, including all registrations and/or applications for the foregoing and (ii) all databases, data collections, protocols, specifications, software, source code and object code, user interfaces, works of authorship, and other forms of technology (whether or not embodied in any tangible form).

"***Inventory***" means inventory, finished goods, raw materials, work in progress, packaging, supplies, parts and other inventories.

"***IT Systems***" means all computer systems, servers, network equipment and other computer hardware owned, leased or licensed Seller or any other Person for the benefit of Seller and used in the Business.

"***Key Contracts***" means the Contracts of Seller listed on Schedule 1.1(a).

"***Knowledge of Seller***" or "***Seller's Knowledge***" or any other similar knowledge qualification means the actual knowledge of Kristi Lovelady, Dan Browning or Jean Browning, in each case, following due and reasonable inquiry concerning the applicable matter.

"***Law***" means any statute, law, ordinance, regulation, rule, code, Order, constitution, treaty, common law, judgment, decree, other requirement or rule of law of any Governmental Authority, but does not include any Permit.

"***Liability***" means any liability, debt, charge, obligation, Tax, deficiency, loss, damage, assessment, claim, cause of action, penalty, fine, guarantee, cost, expense or other charge (including costs of investigation and defense and attorney's fees, costs and expenses) of any kind or nature, in each case, whether direct or indirect, accrued or unaccrued, known or unknown, liquidated or unliquidated, absolute or contingent, matured or unmatured, including those arising under any Law or Proceeding.

"***Losses***" means losses, Liabilities, claims, obligations, deficiencies, demands, judgments, damages, interest, fines, penalties, claims, suits, actions, causes of action, assessments, awards, forfeitures, pecuniary harm, costs and expenses (including costs of investigation and defense and attorneys' and other professionals' fees), whether or not involving a third party claim.

"***Material Adverse Effect***" means any event, effect, occurrence, fact or state of facts, development, condition, circumstance, or change that is materially adverse to (a) the Business, the Purchased Assets, the Assumed Liabilities or the results of operations, financial condition or assets of Seller, taken as a whole, or (b) the ability of Seller to consummate the transactions contemplated hereby; provided, however, that "Material Adverse Effect" shall not include event directly related to: (i) general economic or political conditions; (ii) conditions generally affecting the industry in which Seller operates; (iii) acts of war (whether or not declared), armed hostilities or terrorism, or the escalation or worsening thereof; or (iv) any natural or man-made disaster or acts of God, except, in the case of clauses (i) through (iv), to the extent such events have a disproportionate effect on Seller relative to other Persons engaged in the industry in which Seller operates.

"***Material Contracts***" has the meanings set forth in Section 4.9.

"***Materials of Environmental Concern***" means any material, substance or waste regulated under or subject to liability under any Environmental Law or Medical Waste Law, including anything defined under any Environmental Law as a "pollutant," "contaminant," "hazardous material," "hazardous substance," or "hazardous waste," and Medical Waste, petroleum and petroleum products and by-products, asbestos-containing materials, radioactive materials, and polychlorinated biphenyls.

"***Maximum Amount***" has the meaning set forth in Section 9.3(a)(ii).

"***Medical Waste***" means: (a) pathological waste; (b) blood; (c) sharps; (d) wastes from surgery or autopsy; (e) dialysis waste, including contaminated disposable equipment and supplies; (f) cultures and stocks of infectious agents and associated biological agents; (g) isolation wastes; (h) contaminated equipment; (i) laboratory waste; (j) various other biological waste and discarded materials contaminated with or exposed to blood, excretion, or secretions from human beings, and (k) pharmaceutical waste. "Medical Waste" also includes any substance, pollutant, material, or contaminant listed or regulated under the MWTA and any other Medical Waste Law.

"***Medical Waste Law***" means the MWTA, the U.S. Public Vessel Medical Waste Anti-Dumping Act of 1988, 33 U.S.C. § 2501 *et seq*., the Marine Protection, Research, and Sanctuaries Act of 1972, 33 U.S.C. § 1401 *et seq*., The Occupational Safety and Health Act, 29 U.S.C. § 651 *et seq*., the United States Department of Health and Human Services, National Institute for Occupations Self-Safety and Health Infectious Waste Disposal Guidelines, Publication No. 88-119, and any other Laws insofar as they purport to regulate Medical Waste, or impose requirements relating to Medical Waste.

"***Money Laundering Laws***" has the meaning set forth in Section 4.31.

"***MWTA***" means the Medical Waste Tracking Act of 1988, 42 U.S.C. § 6992, *et seq*.

"***No-Shop Restricted Parties***" has the meaning set forth in Section 6.4.

"***Order***" shall mean any injunction (whether temporary, preliminary or permanent), writ, temporary restraining order, ruling, decision, verdict, award, charge, judgment, decree or any order of any nature, in each case of a Governmental Authority (unless otherwise specified).

"***Outside Date***" has the meaning set forth in Section 10.1(c).

"***Party***" means, individually, Buyer or Seller, and "***Parties***" means, collectively, Buyer and Seller.

"***PEO***" means J Solutions Inc.

"***Permit***" means any approval, certificate of authority, accreditation, license, certification, registration, permit, franchise, right, qualification or other authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Authority or pursuant to any Law.

"***Permitted Encumbrances***" means: (a) liens for Taxes not yet due and payable; (b) mechanics', carriers', workmen's, repairmen's or other like liens arising or incurred in the ordinary course of business for amounts that are not delinquent and the existence of which does not, and would not reasonably be expected to, materially impair the marketability, value or use and enjoyment of the asset subject to such Encumbrance; and (c) liens arising under original purchase price conditional sales contracts and equipment leases with third parties entered into in the ordinary course of business.

"***Person***" means any individual, corporation, association, partnership, limited liability company, sole proprietorship, unincorporated or incorporated organization, joint venture, trust, estate, association, labor union, Governmental Authority or other entity.

"***Personal Data***" means: (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or donor or account number, biometric identifiers, device or machine identifier, IP address, or any other piece of information that alone or in combination with other information directly or indirectly collected, held, or otherwise processed by or for Seller allows for the identification or contact with, a natural person or a particular computing device; (ii) any information defined as "personal data", "personally identifiable information", "individually identifiable health information", "protected health information", or "personal information" under any Law; and (iii) any information that is associated, directly or indirectly, with any of the foregoing.

"***PPP Lender***" means BBVA USA.

"***PPP Loan***" means that certain loan, dated May 19, 2020, in the amount of $67,939, issued by the PPP Lender to Seller, pursuant to the U.S. Small Business Administration's ("***SBA***") Paycheck Protection Program established by the CARES Act.

"***PPP Loan Balance***" means the outstanding principal plus accrued but unpaid interest on the PPP Loan outstanding as of the Closing Date.

"***Pre-Closing Tax Period***" means any taxable period ending on or before the Closing Date and, with respect to any taxable period beginning before and ending after the Closing Date, the portion of such taxable period ending on and including the Closing Date.

"***Proceeding***" means any action, claim, suit, complaint, demand, grievance, litigation, dispute, controversy, counterclaim, cause of action, audit, investigation, notice of violation, citation, summon, subpoena or inquiry of any nature, or legal, administrative, arbitration, mediation, or other proceeding, or hearing, whether criminal, civil, regulatory, administrative, judicial, public or private.

"***Prohibited Activities***" has the meaning set forth in Section 8.2(a).

"***Prohibited Fund***" has the meaning set forth in Section 4.17(b).

"***Prohibited Payment***" has the meaning set forth in Section 4.17(b).

"***Purchase Price***" has the meaning set forth in Section 2.5.

"***Representatives***" means, in respect of a Person, such Person's directors, officers, employees, agents, attorneys, representatives, accountants, consultants and other advisors (including advisors retained or engaged by such Person in connection with the transactions contemplated under this Agreement).

"***Restricted Territory***" means the United States of America.

"***Scrap Inventory***" means the Inventory of Seller that was not maintained at all times at the required temperatures.

"***Seller***" has the meaning set forth in the preamble to this Agreement.

"***Seller Account***" means the bank account identified by Seller in writing (which identification shall be made by Seller no later than three (3) Business Days prior to the Closing Date).

"***Seller Disclosure Schedules***" means the disclosure schedules delivered by Seller to Buyer concurrently with the execution and delivery of this Agreement.

"***Seller Fundamental Representations***" means (a) the representations and warranties of Seller set forth in Section 4.1 (Organization; Good Standing of Seller), Section 4.2 (Capitalization; Organizational Documents), Section 4.4 (Consents; Absence of Conflicts), Section 4.5 (Due Execution), Section 4.10 (Title; Sufficiency of Assets), Section 4.18 (FDA Compliance), Section 4.19 (Privacy Matters), Section 4.22 (Tax Liabilities), Section 4.23 (Employee Benefit Plans and Related Matters), Section 4.25 (Environmental Matters), and Section 4.28 (Brokers) of this Agreement.

"***Seller Indemnified Party***" has the meaning set forth in Section 9.2.

"***Seller Indemnifying Parties***" means Seller and the Seller Shareholders.

"***Seller Intellectual Property Assets***" means all Intellectual Property Assets owned or purported to be owned by Seller.

"***Seller Non-Fundamental Representations***" means the representations and warranties of Seller set forth in this Agreement or any other Transaction Document, other than the Seller Fundamental Representations.

"***Seller Shareholders***" means all of the shareholders of Seller (each, a "***Seller Shareholder***") and all of whom are identified on Schedule 1.1(b).

"***Straddle Period***" means any taxable period that includes (but does not end on) the Closing Date.

"***Tangible Personal Property***" has the meaning set forth in Section 2.1(e).

"***Tax Claim***" has the meaning set forth in Section 8.3(c).

"***Tax Clearance Certificate***" has the meaning set forth in Section 8.3(b).

"***Tax Return***" means any return, declaration, report, claim for refund, or information return or statement or other documents relating to Taxes, including any schedule or attachment thereto, and including any amendment thereof.

"***Taxes***" means (a) any and all federal, state, local, foreign and other income, gross receipts, sales, use, ad valorem, capital gains, unclaimed property or escheat, transfer, franchise, profits, license, lease, rent, service, service use, withholding, payroll, employment, excise, severance, privilege, stamp, occupation, premium, property, windfall profits, alternative minimum, estimated, customs, duties or other taxes, fees, assessments or charges of any kind whatsoever, together with any interest and penalties, additions to tax or additional amounts with respect thereto, (b) any Liability for payment of amounts described in clause (a) as a result of transferee Liability or otherwise through operation of law, and (c) any Liability for the payment of amounts described in clauses (a) or (b) as a result of any tax sharing, tax indemnity or tax allocation agreement or any other express or implied agreement to indemnify any other Person.

"***Third Party Licensed IP***" has the meaning set forth in Section 4.12(a) below.

"***Transaction Documents***" means this Agreement, the Consulting Agreement, the Employment Agreements, the Bill of Sale, the Assignment and Assumption Agreement, the Intellectual Property Assignment, the Deed, the Transition Services Agreement, and the other agreements, instruments and documents required to be delivered hereunder.

"***Transfer Taxes***" has the meaning set forth in Section 8.3(a).

"***WARN Act***" means the Worker's Adjustment and Retraining Notification Act of 1988, and any applicable similar state and local law, as amended from time to time, and any regulations and guidance issued pursuant thereto.

Section 1.2 **Interpretation**. In this Agreement, unless the context otherwise requires:

(a) reference the singular number includes the plural number and vice versa;

(b) reference to any Person includes such Person's successors and assigns but, if applicable, only if such successors and assigns are permitted by this Agreement, and references to a Person in a particular capacity excludes such Person in any other capacity;

(c) reference to any gender includes each other gender;

(d) reference to any agreement (including this Agreement), document or instrument means such agreement, document or instrument as amended or modified (including any waiver or consent) and in effect from time to time in accordance with the terms thereof and, if applicable, the terms hereof;

(e) reference to any Article, Section, Schedule or Exhibit means such Article, Section, Schedule or Exhibit of or to this Agreement, and references in any Article, Section, Schedule, Exhibit or definition to any clause means such clause of such Article, Section, Schedule, Exhibit or definition;

(f) any accounting term used and not otherwise defined in this Agreement or any Transaction Document has the meaning assigned to such term in accordance with GAAP, as consistently applied by Seller;

(g) references to GAAP or any Law refers to GAAP or such Law as of the date hereof and the Closing Date, including, without limitation, any amendments thereto as of such dates;

(h) the words "this Agreement," "herein," "hereby," "hereunder," "hereof," "hereto" and words of similar import are references to this Agreement as a whole and not to any particular Section or other provision hereof, unless expressly so limited;

(i) the word "including" and its derivatives means "including, but not limited to," and corresponding derivative expressions;

(j) relative to the determination of any period of time, "from" means "from and including," "to" means "to but excluding" and "through" means "through and including;"

(k) no consideration shall be given to the captions of the articles, sections, subsections, or clauses, which are inserted for convenience in locating the provisions of this Agreement and not as an aid in its construction;

(l) no consideration shall be given to the fact or presumption that one Party had a greater or lesser hand in drafting this Agreement; every covenant, term and provision of this Agreement shall be construed simply according to its fair meaning and not strictly for or against any Party (notwithstanding any rule of law requiring an agreement to be strictly construed against the drafting party), it being understood that the Parties to this Agreement are sophisticated and have had adequate opportunity and means to retain counsel to represent their interests and to otherwise negotiate the provisions of this Agreement;

(m) examples shall not be construed to limit, expressly or by implication, the matter they illustrate;

(n) a defined term has its defined meaning throughout this Agreement, and each Exhibit and Schedule to this Agreement, regardless of whether it appears before or after the place where it is defined;

(o) all references to prices, values or monetary amounts refer to United States dollars, unless expressly provided otherwise;

(p) each Exhibit and Schedule to this Agreement is a part of this Agreement, but if there is any conflict or inconsistency between the main body of this Agreement and any Exhibit or Schedule, the provisions of the main body of this Agreement shall prevail; and

(q) the word "or" may not be mutually exclusive, and can be construed to mean "and" where the context requires there to be a multiple rather than an alternative obligation or meaning.

ARTICLE II
PURCHASE AND SALE

Section 2.1 **Purchased Assets**. Subject to the terms and conditions set forth herein, at the Closing, Seller shall sell, assign, transfer, convey and deliver to Buyer, and Buyer shall purchase from Seller, free and clear of any Encumbrances other than Permitted Encumbrances, all of Seller's right, title and interest in, to and under all of the assets, properties and rights of every kind and nature, whether real, personal or mixed, tangible or intangible (including goodwill), wherever located and whether now existing or hereafter acquired (other than the Excluded Assets), which relate to, or are used or held for use in connection with, the Business (collectively, the "***Purchased Assets***"), including, without limitation, the following:

(a) all Inventory existing as of the Closing Date other than the Scrap Inventory ("***Acquired Inventory***");

(b) all Contracts set forth on Schedule 2.1(b) (the "***Assigned Contracts***");

(c) all Seller Intellectual Property Assets;

(d) all Third Party Licensed IP;

(e) all furniture, fixtures, equipment, machinery, tools, vehicles, office equipment, supplies, computers, telephones and other tangible personal property (the "***Tangible Personal Property***");

(f) the Real Property;

(g) all Permits which are held by Seller and required for the conduct of the Business as currently conducted or for the ownership and use of the Purchased Assets;

(h) all rights to any Proceedings of any nature available to or being pursued by Seller to the extent related to the Business, the Purchased Assets or the Assumed Liabilities, whether arising by way of counterclaim or otherwise;

(i) all prepaid expenses, credits, advance payments, claims, security, refunds, rights of recovery, rights of set-off, rights of recoupment, deposits, charges, sums and fees (including any such item relating to the payment of Taxes);

(j) all of Seller's rights under warranties, indemnities and all similar rights against third parties to the extent related to any Purchased Assets;

(k) the Business Insurance Policies and all insurance benefits, including rights and proceeds, arising from or relating to the Business, the Purchased Assets or the Assumed Liabilities;

(l) originals, or where not available, copies, of all books and records, including, but not limited to, books of account, ledgers and general, financial and accounting records, machinery and equipment maintenance files, customer lists, customer purchasing histories, price lists, distribution lists, supplier lists, donor lists, quality control records and procedures, customer or donor complaints and inquiry files, research and development files, records and data (including all correspondence with any Governmental Authority), sales material and records (including pricing history, total sales, terms and conditions of sale, sales and pricing policies and practices), strategic plans, internal financial statements, marketing and promotional surveys, material and research and files relating to the Seller Intellectual Property Assets and Third Party Licensed IP ("***Books and Records***"); and

(m) all goodwill and the going concern value of the Business.

Section 2.2 **Excluded Assets**. Notwithstanding the foregoing, the Purchased Assets shall not include the following assets (collectively, the "***Excluded Assets***"):

(a) Contracts that are not Assigned Contracts (the "***Excluded Contracts***");

(b) the corporate seals, organizational documents, minute books, stock books, Tax Returns, books of account or other records having to do with the corporate organization of Seller;

(c) all Benefit Plans sponsored by Seller and any assets, rights, Contracts, or agreements attributable thereto;

(d) all Inventory other than Acquired Inventory; and

(e) the rights which accrue or will accrue to Seller under this Agreement and the Ancillary Documents.

Section 2.3 **Assumed Liabilities**. Subject to the terms and conditions set forth herein, Buyer shall assume and agree to pay, perform and discharge only the Liabilities of Seller in respect of the Assigned Contracts, but only to the extent that such Liabilities thereunder are required to be performed after the Closing Date, were incurred in the ordinary course of business and do not relate to any failure to perform, improper performance, warranty or other breach, default or violation by Seller on or prior to the Closing (collectively, the "***Assumed Liabilities***").

Section 2.4 **Excluded Liabilities**. Notwithstanding the provisions of Section 2.3 or any other provision in this Agreement to the contrary, Buyer shall not assume and shall not be responsible to pay, perform or discharge any Liabilities of Seller or any of its Affiliates of any kind or nature whatsoever other than the Assumed Liabilities (the "***Excluded Liabilities***"). Seller shall, and shall cause each of its Affiliates to, pay and satisfy in due course all Excluded Liabilities which they are obligated to pay and satisfy. Without limiting the generality of the foregoing, the Excluded Liabilities shall include, but not be limited to, the following:

(a) any Liabilities of Seller arising or incurred in connection with the negotiation, preparation, investigation and performance of this Agreement, the other Transaction Documents and the transactions contemplated hereby and thereby, including, without limitation, fees and expenses of counsel, accountants, consultants, advisers and others;

(b) any Liability for (i) Taxes of Seller (or any shareholder or Affiliate of Seller) or relating to the Business, the Purchased Assets or the Assumed Liabilities for any Pre-Closing Tax Period; (ii) Taxes that arise out of the consummation of the transactions contemplated hereby or that are the responsibility of Seller pursuant to Section 8.3(a); or (iii) other Taxes of Seller (or any shareholder or Affiliate of Seller) of any kind or description (including any Liability for Taxes of Seller (or any shareholder or Affiliate of Seller) that becomes a Liability of Buyer under any common law doctrine of de facto merger or transferee or successor liability or otherwise by operation of contract or Law);

(c) any Liabilities relating to or arising out of the Excluded Assets;

(d) any Liabilities in respect of any pending or threatened Proceeding (including, without limitation, any pending or threatened Federal or state agency-initiated action) arising out of, relating to or otherwise in respect of the operation of the Business or the Purchased Assets to the extent such Proceeding relates to such operation on or prior to the Closing Date;

(e) any product Liability or similar claim for injury to a Person which arises out of or is based upon any express or implied representation, warranty, agreement or guaranty made by Seller, or by reason of the improper performance of a product, improper design or manufacture, failure to adequately package, label or warn of hazards or other related product defects of any products at any time manufactured or sold or any service performed by Seller;

(f) any Liabilities of Seller for any present or former employees, officers, directors, retirees, independent contractors or consultants of Seller, including, without limitation, any Liabilities associated with any claims for wages or other benefits, bonuses, accrued vacation, workers' compensation, severance, retention, termination or other payments;

(g) any Environmental Claims, or Liabilities under Environmental Laws, to the extent arising out of or relating to facts, circumstances or conditions existing on or prior to the Closing or otherwise to the extent arising out of any actions or omissions of Seller;

(h) all trade accounts payable of Seller;

(i) any Liabilities of the Business relating or arising from unfulfilled commitments, purchase orders, or customer orders that (i) do not constitute part of the Purchased Assets issued by the Business' customers to Seller on or before the Closing; (ii) did not arise in the ordinary course of business; or (iii) are not validly and effectively assigned to Buyer pursuant to this Agreement;

(j) any Liabilities to indemnify, reimburse or advance amounts to any present or former officer, director, employee or agent of Seller (including with respect to any breach of fiduciary obligations by same), except for indemnification of same pursuant to Section 9.2 as Seller Indemnified Parties;

(k) any Liabilities under the Excluded Contracts or any other Contracts, (i) which are not validly and effectively assigned to Buyer pursuant to this Agreement; (ii) which do not conform to the representations and warranties with respect thereto contained in this Agreement; or (iii) to the extent such Liabilities arise out of or relate to a breach by Seller of such Contracts prior to Closing;

(l) any Liabilities associated with debt, loans or credit facilities of Seller and/or the Business owing to financial institutions;

(m) any Liabilities associated with the Benefit Plans sponsored by Seller; and

(n) any Liabilities arising out of, in respect of or in connection with the failure by Seller or any of its Affiliates to comply with: (i) any Law (including, without limitation, any failure to comply with any FDA regulations); (ii) any Order; (iii) any Permit; or (iv) customer standards and quality requirements.

Section 2.5 **Purchase Price**. The aggregate consideration payable by Buyer for the purchase and sale of the Purchased Assets is: (a) USD $1,500,000 (the "***Base Purchase Price***"), as adjusted pursuant to Section 2.6; plus (b) an amount equal to the number of liters of Acquired Inventory as of the Closing Date multiplied by $262.50 per liter (the sum of the amounts set forth in clauses (a) and (b), the "***Purchase Price***"); plus (b) the assumption of the Assumed Liabilities. The Purchase Price shall be payable as follows:

(a) on the Closing Date, Buyer shall pay to Seller an amount equal to the Base Purchase Price minus the PPP Loan Balance minus the Holdback Amount minus the Destruction Costs (the "***Closing Payment***"), which shall be payable by wire transfer, in immediately available funds, to the Seller Account; and

(b) on the first anniversary of the Closing Date, Buyer shall pay to Seller the Holdback Amount (less any offset thereto made in accordance with this Agreement), which shall be payable by wire transfer, in immediately available funds, to the Seller Account.

Section 2.6 **Purchase Price Adjustment for Real Property Matters**. For the avoidance of doubt, non-delinquent: (a) real property Taxes, assessments, water charges and sewer rents, if any; and (b) prepaid expenses, credits, advance payments and security deposits shall be apportioned between Seller and Buyer as of midnight on the day prior to the Closing Date with respect to the Real Property, in each case, based on a fiscal period for which assessed, based upon the most recent available tax duplicate and in accordance with local custom, which apportionment shall be final.

Section 2.7 **Purchase Price Allocation**. Seller and Buyer agree that the Purchase Price and Assumed Liabilities (plus other relevant items) shall be allocated amongst the Purchased Assets for Tax purposes as shown on the allocation schedule (the "***Allocation Schedule***"). Within ninety (90) days of the Closing Date, Seller shall provide Buyer with a proposed Allocation Schedule, which allocates the Purchase Price and Assumed Liabilities (plus other relevant items) among the Purchased Assets in accordance with Section 1060 of the Code and the Treasury Regulations thereunder (and any similar provision of state, local or foreign law, as appropriate); provided, however, the Buyer and Seller hereby acknowledge and agree that the Real Property shall be valued at $81,712. Buyer shall have the ability to review, comment and approve such Allocation Schedule. If Buyer does not object to the Seller's proposed Allocation Schedule within thirty (30) days of receipt of the Allocation Schedule, Buyer shall be deemed to have approved such Allocation Schedule. Buyer and Seller will resolve any disagreement regarding the Allocation Schedule in good faith and, if they are unable to do so within fifteen (15) days after any objection from Buyer, the matter shall be submitted to the Independent Accounting Firm. If there are any post-Closing adjustments to the Purchase Price, Seller and Buyer shall cooperate with each other in good faith to agree on an amendment to the Allocation Schedule. Buyer and Seller agree to file all applicable income Tax Returns (including, without limitation, IRS Form 8594) consistent with the Allocation Schedule (as amended pursuant to this Section 2.7), except to the extent the allocation reflected therein is subsequently adjusted pursuant to an audit by the Internal Revenue Service or a court decision.

Section 2.8 **Withholding**. Buyer and any other withholding agent shall be entitled to deduct and withhold from any amounts paid in connection with the transactions contemplated by this Agreement any amounts required under any applicable law to be deducted and withheld, and any such amounts will be treated for all purposes of this Agreement as having been made to the Person in respect of which such deduction and withholding was made.

Section 2.9 **Third Party Consents**. To the extent that Seller's rights under any Contract or Permit constituting a Purchased Asset, or any other Purchased Asset, may not be assigned to Buyer without the consent of another Person which has not been obtained, this Agreement shall not constitute an agreement to assign the same if an attempted assignment would constitute a breach thereof or be unlawful, and Seller, at its expense, shall use its best efforts to obtain any such required consent(s) as promptly as possible. If any such consent shall not be obtained or if any attempted assignment would be ineffective or would impair Buyer's rights under the Purchased Asset in question so that Buyer would not in effect acquire the benefit of all such rights, Seller, to the maximum extent permitted by law and the Purchased Asset, shall act after the Closing as Buyer's agent in order to obtain for Buyer the benefits thereunder and shall cooperate, to the maximum extent permitted by Law and the Purchased Asset, with Buyer in any other reasonable arrangement designed to provide such benefits to Buyer. Notwithstanding any provision in this Section 2.9 to the contrary, Buyer shall not be deemed to have waived its rights under Section 7.2 hereof unless and until Buyer either provides written waivers thereof or elects to proceed to consummate the transactions contemplated by this Agreement at Closing.

ARTICLE III
CLOSING

Section 3.1 **Closing**. The consummation of the sale and purchase of the Purchased Assets and the other transactions contemplated by this Agreement (the "***Closing***") shall take place at the offices of Jackson Walker L.L.P., 1401 McKinney, Suite 1900, Houston, Texas 77010, or such other place and in such other manner (electronic exchange of documents or otherwise) as shall be mutually agreed upon in writing by the Parties hereto, at 9:00 a.m. Houston, Texas time on the second Business Day after all of the conditions to Closing set forth in Article VII (other than conditions that are intended to be satisfied at the Closing) have been satisfied or waived, as applicable, or at such other time or date as Seller and Buyer may mutually agree upon in writing. The date on which Closing is to occur is referred to herein as the "***Closing Date***".

Section 3.2 **Deliveries of Seller at Closing**. At or prior to the Closing, Seller shall deliver (or shall have delivered), or cause to be delivered, to Buyer the following:

(a) a bill of sale in the form of **Exhibit D** hereto (the "***Bill of Sale***") and duly executed by Seller, transferring the tangible personal property included in the Purchased Assets to Buyer;

(b) an assignment and assumption agreement in the form of **Exhibit E** hereto (the "***Assignment and Assumption Agreement***") and duly executed by Seller, effecting the assignment to and assumption by Buyer of the Purchased Assets and the Assumed Liabilities;

(c) an assignment in the form of **Exhibit F** hereto (the "***Intellectual Property Assignments***") and duly executed by Seller, transferring all of Seller's right, title and interest in and to the Seller Intellectual Property Assets and Third Party Licensed IP to Buyer;

(d) with respect to the Real Property, a special warranty deed in form of **Exhibit G** hereto (each, a "***Deed***") and duly executed and notarized by Seller;

(e) the Transition Services Agreement in the form of **Exhibit H** hereto (the "***Transition Services Agreement***") and duly executed by Seller;

(f) the Consulting Agreement duly executed by Kristi Lovelady;

(g) the Employment Agreements duly executed by Dan Browning and Jean Browning;

(h) a certificate of a duly authorized officer of Seller certifying as to (i) the resolutions of the board of directors of Seller and Seller Shareholders, each approving and authorizing the execution, delivery and performance of this Agreement and each other agreement contemplated herein to which Seller is a party and the transactions contemplated hereby and thereby; (ii) the Articles of Incorporation of Seller; (iii) the bylaws of Seller; and (iv) the signature and incumbency of any officer or other representative executing this Agreement and the other Transaction Documents;

(i) a certificate of an officer of Seller certifying the satisfaction of the conditions set forth in Section 7.2(b) and Section 7.2(d);

(j) a certificate of existence and good standing (or its functional equivalent) of Seller and Seller from the Secretary of State of Texas, dated as of a recent date prior to the Closing;

(k) a certificate of no tax due issued by the Texas Comptroller of Public Accounts;

(l) a duly executed written certificate from Seller in a form reasonably acceptable to Buyer certifying that Seller is not a foreign person within the meaning of Treasury Regulation section 1.1445-2(b) and complying with the requirements of said Treasury Regulation.

(m) receipt of (i) all consents under Key Contracts, (ii) evidence of successful transfer of all Permits to Buyer, including in connection with the CHOW, and (iii) transfers to Buyer, or the making of all filings for the benefit of Buyer, in respect of all other consents, notices and authorizations required to ensure the ownership and operation by Buyer, immediately following the Closing (as owned and operated by Seller immediately prior to the Closing), of the Business and the Purchased Assets.

Section 3.3 **Deliveries of Buyer at Closing**. At the Closing, Buyer shall deliver, or cause to be delivered, the following:

(a) to Seller, the Closing Payment in accordance with Section 2.5(a);

(b) to PPP Lender, the PPP Loan Balance, payable by wire transfer, in immediately available funds, to the account designated by PPP Lender, which amount shall be held in escrow by PPP Lender pursuant to an Escrow Agreement in form and substance acceptable to PPP Lender, Seller and Buyer;

(c) to Seller, the Consulting Agreement, duly executed by Buyer;

(d) to Seller, the Employment Agreements, duly executed by Buyer;

(e) to Seller, the Assignment and Assumption Agreement, duly executed by Buyer;

(f) to Seller, the Transition Services Agreement, duly executed by Buyer; and

(g) to Seller, a certificate of the sole manager of Buyer certifying the satisfaction of the conditions set forth in Section 7.3(b) and Section 7.3(c).

ARTICLE IV
REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Buyer that the statements contained in this Article IV are true and correct as of the date hereof and as of the Closing Date, except: (i) for representations or warranties made with respect to a specified date (in which case the applicable representations or warranties shall be true and correct only as of such specified date), and (ii) as set forth in the Seller Disclosure Schedules (the parts of which are numbered to correspond to the particular Section or subsection of this Agreement to which the information set forth in the Seller Disclosure Schedules relates):

Section 4.1 **Organization; Good Standing of Seller**. Seller is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Texas. Seller is not required to be qualified or licensed to transact business as a foreign corporation in any other jurisdiction. Seller has the requisite power and authority to enter into this Agreement and the other Transaction Documents to which it is a party, perform its obligations hereunder and thereunder, own, lease, and operate its properties and assets (including the Purchased Assets) and to conduct its businesses as currently conducted.

Section 4.2 **Capitalization**. The Seller Shareholders are all of the record and beneficial owners of 100% of issued and outstanding capital stock of Seller, free and clear of all Encumbrances. There are no outstanding or authorized options, warrants, convertible securities, derivative or phantom securities or other rights, agreements, arrangements or commitments of any character (including any subscriptions, preemptive rights, equity appreciation rights, rights of first refusal, or call rights) relating to any capital stock of Seller or obligating Seller or Seller to issue, sell, deliver or cause to be issued, sold or delivered, any capital stock, or any other interest, in Seller. There are no voting trusts, proxies or other agreements or understandings in effect with respect to the voting or transfer of any of the capital stock of Seller.

Section 4.3 **No Subsidiaries**. Seller does not own or have any equity interest in any other Person.

Section 4.4 **Consents; Absence of Conflicts With Other Agreements, Etc.** The execution, delivery and performance by Seller of this Agreement and the other Transaction Documents to which Seller is a party, and the consummation of the transactions contemplated hereby and thereby: (a) are not in contravention of the terms of any of the articles of incorporation or bylaws of Seller; (b) will neither constitute a violation or breach of or a default under, or conflict with, any Law or any term or provision of any Contract to which Seller is a party or by which Seller is bound; (c) result in the creation of any Encumbrance under, or constitute or create a right of acceleration, termination, or amendment, or create the right to a change of control payment under any Contract; and (d) except as set forth on Schedule 4.4, do not require Seller to obtain any approval, consent of, waiver or authorization from, exemption by, or give notice to or make any filing with any other Person.

Section 4.5 **Due Execution; Binding Agreement**. This Agreement and, when executed by Seller, the other Transaction Documents to which Seller is a party, (a) have been duly authorized by all corporate action on the part of Seller and duly executed and delivered by Seller and (b) assuming due authorization, execution and delivery by Buyer, are or will constitute the valid and legally binding obligation of Seller and will be enforceable against Seller in accordance with the respective terms hereof or thereof, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general principles of equity (regardless of whether enforcement is sought in a proceeding at law or in equity).

Section 4.6 **Financial Statements; No Undisclosed Liabilities**.

(a) Schedule 4.6(a) contains, and Seller has made available to Buyer true, correct and complete copies of the unaudited financial statements for the Business consisting of the balance sheet as at December 31 in each of the years 2017, 2018 and 2019 and the related statements of income for the years then ended (the "***Annual Financial Statements***"), and unaudited financial statements for the Business consisting of the balance sheet as at September 30, 2020 and the related statements of income for the nine-month period then ended (the "***Interim Financial Statements***" and together with the Annual Financial Statements, the "***Financial Statements***"). The Financial Statements have been prepared in accordance with GAAP applied on a consistent basis throughout the period involved, subject, in the case of the Interim Financial Statements, to normal and recurring year-end adjustments (the effect of which will not be materially adverse) and the absence of notes (that, if presented, would not differ materially from those presented in the Annual Financial Statements). To the Knowledge of Seller, the Financial Statements have been prepared based on the books and records of the Business, and fairly present in all material respects the financial condition of the Business as of the respective dates they were prepared and the results of the operations of the Business for the periods indicated. The balance sheet of the Business as of December 31, 2019 is referred to herein as the "***Balance Sheet***" and the date thereof as the "***Balance Sheet Date***" and the balance sheet of the Business as of September 30, 2020 is referred to herein as the "***Interim Balance Sheet***" and the date thereof as the "***Interim Balance Sheet Date***". Seller maintains a standard system of accounting for the Business established and administered in accordance with GAAP. None of Seller or its personnel who have a role in the preparation of financial statements or the internal accounting controls utilized by Seller has identified or been made aware of (i) any significant deficiency or material weakness in the system of internal accounting controls utilized by Seller, (ii) any fraud, whether or not material, that involves the management of Seller or any of its personnel or (iii) any claim or allegation regarding any of the foregoing.

(b) Seller does not have any Liabilities or obligations other than Liabilities or obligations (i) reflected and reserved against in the Interim Financial Statements or (ii) incurred in the ordinary course of business since the Interim Balance Sheet Date that are not individually or in the aggregate material in amount and do not constitute any breach of any Law.

Section 4.7 **Accounts Receivable; Accounts Payable**.

(a) All of the accounts receivable of Seller (i) represent bona fide and valid obligations arising from sales actually made or services actually performed by Seller in the ordinary course of business consistent with past practice, (ii) are valid and enforceable claims, (iii) to the Knowledge of Seller, are collectible in full within 60 days after billing, and (iv) are subject to no set-off or counterclaim. Since the Balance Sheet Date, Seller has collected its accounts receivable in the ordinary course of business and in a manner which is consistent with past practices and has not accelerated any such collections. Except as set forth on Schedule 4.7(a), Seller does not have any accounts receivable or loans receivable from any Affiliate of Seller, any Seller Shareholder or any director, officer, employee or consultant of Seller.

(b) All accounts payable and notes payable of Seller arose in bona fide arm's length transactions in the ordinary course of business consistent with past practice and no such account payable or note payable is delinquent in its payment. Since the Balance Sheet Date, Seller has paid its accounts payable in the ordinary course of business and in a manner which is consistent with its past practices. Except as set forth on Schedule 4.7(b), Seller does not have any account payable to any Affiliate of Seller, any Seller Shareholder or any director, officer, employee or consultant of Seller. As of the Closing Date, Seller shall have paid all outstanding accounts payable and notes payable.

Section 4.8 **Inventory**. To the Knowledge of Seller, all Inventory, whether or not reflected in the Balance Sheet, consists of a quality and quantity usable and salable in the ordinary course of business consistent with past practice. All Inventory is owned by Seller free and clear of all Encumbrances. The quantities of each item of Inventory (whether raw materials, work-in-process or finished goods) are not excessive, but are reasonable in the present circumstances of Seller.

Section 4.9 **Material Contracts; No Defaults**. Schedule 4.9 contains a true, correct, and complete list (including a summary of the material terms of any oral Contract) of each Contract to which Seller is a party or to which any of the Purchased Assets are subject (collectively, the "***Material Contracts***"), including:

(a) Contracts limiting or restraining Seller from engaging or competing in any lines of business with any other Person in any market or geographic area;

(b) Contracts relating to any acquisition to be made by Seller of any operating business or the capital stock of any other Person;

(c) other than relating to trade payables, Contracts relating to the incurrence by Seller of Indebtedness, or the making of any loans to another Person or guarantees with respect to Indebtedness of another Person;

(d) any Contract under which any Purchased Asset serves as security or collateral for Indebtedness owed to any other Person;

(e) Contracts which involve the expenditure by Seller of more than $10,000 in the aggregate or require performance by any party more than one year from the date hereof that, in either case, is not terminable by Seller without material penalty on notice of 30 days' or less;

(f) all employment or similar service agreements between Seller and any director, officer or employee of Seller (including those that may be co-employed with PEO);

(g) all collective bargaining or similar collective or labor agreements relating to any service providers of Seller (including those that may be co-employed with PEO);

(h) any Contract that relates to the Seller's relationship with the PEO;

(i) Contracts for the lease (i) by Seller of any real or personal property (except personal property leases and installment and conditional sales agreements providing for aggregate annual payments of less than $1,000), or (ii) of the Real Property;

(j) any Contract with any third party, the payments to which has represented 5% or more of the expenditures of Seller on supplied goods or services in the most recent twelve (12)-month period;

(k) any Contract that relates to the acquisition or divestiture of assets (i) that is material to the operation of the business of Seller, or all of them taken as a whole, (ii) under which Seller has any Liability with respect to an "earn-out", contingent purchase price, deferred purchase price or similar contingent payment obligation, or (iii) that provides for the grant to any Person of any preferential rights to purchase any of the assets of Seller;

(l) any Contract that relates to the distribution, marketing, advertising or sale, or referral of Seller's products or services, in each case which involved payments by Seller in excess of $1,000 in the most recent twelve (12) month period or is reasonably expected to involve payments by Seller in excess of $1,000 in the twelve (12) month period ending on the first anniversary of the date hereof;

(m) any Contract that is a joint venture or collaboration agreement with any Person;

(n) any Contract in the most recent twelve (12) month period with any independent contractor or consultant under which Seller has made aggregate payments of $10,000 or more;

(o) any settlement agreement or consent decree entered into between Seller and any current or former employee of Seller or any other Person (including any Governmental Authority);

(p) any Contract providing that Seller indemnify any Person (other than such Contracts entered into in the ordinary course of business for amounts less than $1,000), or any Contract requiring Seller to assume any Tax, environmental or other Liability of another Person;

(q) any Contract that requires any capital commitment or capital expenditure, individually or in the aggregate, by Seller in excess of $5,000;

(r) any Contract under which "most favored nation" pricing provisions or any similar provision requiring that a third party (including any insurance company) be offered terms or concessions at least as favorable as those offered to one or more Persons;

(s) any Contract that requires Seller to purchase its total requirements of any product or service from any third party, that contains any exclusivity provision in favor of the counterparty thereto or that contains a "take or pay" provision;

(t) all Contracts relating to Seller Intellectual Property Assets or Third Party Licensed IP to which Seller is a party;

(u) all Contracts creating an Encumbrance on any Purchased Assets other than Permitted Encumbrances;

(v) all Contracts between or among Seller on the one hand and any Seller Shareholder or any Affiliate of Seller on the other hand;

(w) any Contract related to the Business, to which Seller is not a party;

(x) any Contract not otherwise of a type listed above involving reasonably anticipated aggregate payments to or from Seller in excess of $1,000 annually, and which does not expire in all respects prior to the Closing.

Seller is not in default under or in breach of, or in receipt of any written claim of default under or breach of, any Material Contract. To the Knowledge of Seller, there is not, in respect of any other party under any of the Material Contracts, any existing default, event of default, breach or other similar event. Each of the Material Contracts is in full force and effect and constitutes a valid and binding obligation of Seller, enforceable against Seller, and, to the Knowledge of the Seller, against the other party or parties thereto, in accordance with its terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar Laws relating to creditors' rights generally or by principles of equity.

Section 4.10 **Title; Sufficiency of Assets**. Except as set forth on Schedule 4.10 with respect to leased Tangible Personal Property, Seller has good, valid and marketable title to all Tangible Personal Property reflected in the Interim Balance Sheet and acquired after the Interim Balance Sheet Date, other than properties and assets sold or otherwise disposed of in the ordinary course of business, consistent with past practice, since the Interim Balance Sheet Date. Seller has a valid leasehold interest in the leased Tangible Personal Property described on Schedule 4.10. All Purchased Assets are free and clear of Encumbrances other than Permitted Encumbrances. Upon the transfer to Buyer of the Purchased Assets, Seller will have delivered to Buyer all of the properties, assets, rights and entitlements (including rights to goods, services or supplies from third parties) that are necessary to conduct the Business as currently conducted by Seller. There are no material properties, assets, rights or entitlements related to the Business which are not owned or leased, and at and immediately following the Closing will not be owned or leased, by Buyer, free and clear of any Encumbrances, other than Permitted Encumbrances.

Section 4.11 **Real Property**. Schedule 4.11(a) describes each parcel of real property owned by Seller and used in or necessary for the conduct of the Business as currently conducted (together with all buildings, fixtures, structures and improvements situated thereon and all easements, rights-of-way and other rights and privileges appurtenant thereto, collectively, the "***Real Property***"), including with respect to each property, the address location and use. Seller has delivered to Buyer copies of the deeds and other instruments (as recorded) by which Seller acquired the Real Property, and copies of all title insurance policies, opinions, abstracts and surveys in the possession of Seller with respect to such parcel. Seller does not lease any real property. With respect to each parcel of Real Property: (a) Seller has good and marketable fee simple title, free and clear of all Encumbrances, except Permitted Encumbrances; (b) Seller has not leased or otherwise granted to any Person the right to use or occupy the Real Property or any portion thereof; and (c) there are no unrecorded outstanding options, rights of first offer or rights of first refusal to purchase the Real Property or any portion thereof or interest therein. Seller has not received any written notice of (x) violations of building codes and/or zoning ordinances or other governmental or regulatory Laws affecting the Real Property, (y) existing, pending or threatened condemnation proceedings affecting the Real Property, or (z) existing, pending or threatened zoning, building code or other moratorium proceedings, or similar matters that could reasonably be expected to adversely affect the ability to operate the Real Property. Except as set forth on Schedule 4.11(b), neither the whole nor any material portion of any Real Property has been damaged or destroyed by fire or other casualty, and the Real Property is sufficient for the continued conduct of the Business after the Closing in substantially the same manner as conducted prior to the Closing and constitutes all of the real property necessary to conduct the Business as currently conducted.

Section 4.12 **Intellectual Property; IT Systems**.

(a) Schedule 4.12(a) sets forth all: (i) Seller Intellectual Property Assets that are necessary for or material to the conduct of the Business as currently conducted or as contemplated to be conducted; (ii) all licenses granted by any third party to Seller with respect to Intellectual Property Assets (other than commercially available, off-the-shelf object code software licensed for internal use only under standard terms) ("***Third Party Licensed IP***"); and (iii) all licenses, covenants not to sue, or similar rights granted by Seller to any third party in any Intellectual Property Assets. All Seller Intellectual Property Assets are subsisting; no third party has challenged the validity or enforceability of any Seller Intellectual Property Assets; and, to Seller's Knowledge, all Intellectual Property Assets are valid and enforceable. Seller has taken all reasonable steps to maintain the confidentiality of and to otherwise protect and enforce its rights in all proprietary information, Seller holds, or purports to hold, as a trade secret. Seller owns all right, title, and interest in and to all Seller Intellectual Property Assets, free and clear of all Encumbrances. To the Knowledge of Seller, there is no current unauthorized use, infringement, misappropriation or other violation by a Person of any of Seller Intellectual Property Assets. None of the Seller Intellectual Property Assets is registered or is subject to any application for registration, and Seller does not own, use, market, distribute or license (and has not done any of the foregoing with respect to) any software (including as a software service) other than third party software licensed to Seller for internal use only.

(b) Seller licenses or otherwise possesses rights to use (and Buyer will, after Closing, have all rights necessary to use) the Third Party Licensed IP as needed to conduct the Business as currently conducted without, to the Knowledge of Seller, infringing or violating the valid and enforceable rights of other Persons. Seller has not received any written claims that it has infringed or misappropriated, or has been offered a license to, the Intellectual Property Assets of any third party or has an obligation to indemnify any third party against any infringement, violation or misappropriation of any Intellectual Property Assets of a third party.

(c) No Proceedings are currently pending or, to the Knowledge of Seller, threatened by any Person with respect to any Seller Intellectual Property Assets or Third Party Licensed IP, including any Proceedings challenging the right of Seller to use, possess, transfer, convey or otherwise dispose of any such Intellectual Property Assets.

(d) Schedule 4.12(d) contains a true, correct and complete list of all IT Systems used, operated or maintained by Seller, and whether such IT Systems are owned or leased, or licensed. The IT Systems are adequate and sufficient (including with respect to working condition and capacity) for the operations of the Business. Seller has continuously operated in a manner to preserve and maintain the performance, security and integrity of the IT Systems (and all software, information or data stored on any IT Systems) and maintains reasonable documentation regarding all IT Systems, their methods of operation and their support and maintenance. Except as set forth on Schedule 4.12(d), during the five (5)-year period prior to the date of this Agreement, (i) there has been no failure with respect to any IT Systems that has had a material effect on the operations of Seller, the Business or the Purchased Assets and (ii) there has been no unauthorized access to or use of any IT Systems.

Section 4.13 **Insurance**. Schedule 4.13 sets forth all of the insurance policies that Seller maintains, all of which insurance policies are in full force and effect, with no premium arrearages, bear the policy numbers, are for the terms, with the companies and in the amounts and provide the coverage set forth on Schedule 4.13 (such policies collectively, the "***Business Insurance Policies***"). The Business Insurance Policies are comprised of the types and in the amounts customarily carried by businesses of similar size in the same industry, and, in any event, reflect the maintenance of coverage at least as large as is required by any counterparty under any Material Contract. Seller has made available to Buyer true, correct and complete copies of each such Business Insurance Policy. All premiums relating to such Business Insurance Policies have been timely paid and Seller is in material compliance with all obligations relating to insurance created by Law or any Contract to which Seller is a party. There is no Proceeding pending under any Business Insurance Policy as to which coverage has been questioned, denied or disputed by the underwriters of such policy. Seller has not received any written notice of increase in premiums with respect to, or cancellation or non-renewal of, any of its insurance policies, except for general increases in rates to which similarly situated companies are subject. Seller has timely filed all claims for which it is seeking payment or other coverage under any of its Business Insurance Policies. Seller has not received notice or communication from any insurance company canceling or materially and adversely amending any of such Business Insurance Policies and, to the Knowledge of Seller, no such cancellation or amendment is threatened.

Section 4.14 **Material Customers and Suppliers**.

(a) Schedule 4.14(a) lists the name and address of each vendor, supplier, service provider and other similar business relation of Seller (collectively, "***Suppliers***") and the amount of purchase from each Supplier from whom Seller purchased greater than $1,000 in goods and/or services over the course of each of the twelve (12)-month periods ending December 31, 2019, December 31, 2018 and December 31, 2017. Seller has not received any indication from any such Supplier to the effect that, and Seller has no reason to believe that, any Supplier will stop, materially decrease the rate of, or materially change the terms (whether related to payment, price or otherwise) with respect to, supplying materials, products or services to the Business (whether as a result of the consummation of the transactions contemplated by this Agreement, or otherwise).

(b) Schedule 4.14(b) lists the name and address of each customer and other similar business relation of Seller (collectively, "***Customers***") and the amount of consideration paid by each Customer over the course of each of the twelve (12)-month periods ending December 31, 2019, December 31, 2018 and December 31, 2017. Seller has not received any indication from any such Customer to the effect that, and Seller has no reason to believe that, any Customer will cancel, terminate or materially change the terms (whether related to payment, price or otherwise) with respect to such Customer's relationship with the Business (whether as a result of the consummation of the transactions contemplated by this Agreement, or otherwise).

Section 4.15 **Litigation or Proceedings**. There are no Proceedings pending or, to the Knowledge of Seller, threatened, against or by Seller: (a) relating to or affecting Seller, the Business, the Purchased Assets or the Assumed Liabilities; or (b) that challenge or seek to prevent, enjoin or otherwise delay the transactions contemplated hereby, in each case, at law or in equity, before or by any Governmental Authority, and to the Knowledge of Seller, there is no valid basis for either of the foregoing. There is no Order binding upon Seller or relating to or affecting the Business, the Purchased Assets or Assumed Liabilities.

Section 4.16 **Permits**. Schedule 4.16 contains a list of all Permits held by Seller in connection with the conduct of the Business as currently conducted. Seller possesses all Permits that are required by applicable Law (including all applicable Healthcare Laws) for or that are used in connection with (a) the ownership, lease or operation of the properties of Seller as presently owned, leased or operated, or (b) the conduct of the Business as currently conducted, and all such Permits are valid and in full force and effect, and no revocation, suspension, termination, limitation, or Proceeding is pending, or to the Knowledge of Seller, threatened, to revoke, suspend, terminate or limit any Permit held by Seller. For the past ten (10) years, Seller is and has been in compliance in all material respects with all applicable terms and requirements of each such Permit. To the Knowledge of Seller, no event has occurred that, with or without notice or lapse of time or both, could result in the revocation, suspension, lapse or limitation of any Permit set forth in Schedule 4.16. Seller has not received written notice, or other notice from any Governmental Authority regarding any violation of any such Permit or any revocation, withdrawal, suspension, termination or limitation of any such Permit and Seller has filed all reports and maintained and retained all records required by applicable Laws pertaining to all such Permits.

Section 4.17 **Regulatory Compliance; Improper Payments**.

(a) For the past ten (10) years, Seller, the Business and the Purchased Assets are and have been in compliance in all respects with, and are not in violation of, and have not received written notice from any Governmental Authority regarding any violation of, all Laws applicable to Seller, the Purchased Assets or the conduct of the Business as currently conducted, including, without limitation, all Healthcare Laws. In conducting the Business, Seller has not and does not engage in any unfair or deceptive marketing practices. No claims have been asserted against Seller alleging unfair and/or deceptive marketing practices by Seller or any third party marketing Seller's business and, to the Knowledge of Seller, no such claims are likely to be asserted.

(b) Except to the extent permitted by applicable Law, neither Seller nor any of its shareholders, directors, officers, employees, nor, to the Knowledge of Seller, any agents acting on behalf of or for the benefit of any of the foregoing, has directly or indirectly: (i) offered, paid or received any remuneration, in cash or in kind, to, or made any financial arrangements, with any past or present suppliers, medical staff members or contractors of Seller in exchange for business or payments from such Persons; (ii) given or agreed to give, received or agreed to receive, any gift or gratuitous payment of any kind, nature or description (whether in money, property or services) to any supplier or potential supplier, donor, contractor or any other Person in exchange for business or payments; (iii) made, or agreed to make or authorized the payment or giving of, any bribe, rebate, payoff, influence payment, kickback or other payment or gift of funds or anything of value (including meals or entertainment), contribution, or property to, or for the private use of, any officer, employee or ceremonial office holder of any Governmental Authority, any political party or any political candidate, or any other Person who is connected or associated personally with any of the foregoing; (iv) violated or is in violation of the U.S. Foreign Corrupt Practices Act (the "***FCPA***") or any other applicable Laws regarding bribery, illegal payments and gratuities (collectively with the FCPA, the "***Improper Payment Laws***"); (v) been subject to any investigation by any Governmental Authority with regard to any actual or alleged payment under any Improper Payment Law (a "***Prohibited Payment***"); or (vi) used funds or other assets, or made any promise or undertaking in such regard, for the establishment or maintenance of a secret or unrecorded fund intended to be used to make a Prohibited Payment (a "***Prohibited Fund***"); or (vii) made any false or fictitious entries in any books or records of Seller relating to any Prohibited Payment or Prohibited Fund.

(c) Except as permitted by applicable Law, neither Seller nor any of its shareholders, directors, officers, employees, nor, to the Knowledge of Seller, any agents acting on behalf of or for the benefit of any of the foregoing is a party to any Contract (including but not limited to any joint venture or consulting agreement) with any physician, physical or occupation therapist, health care facility, hospital, nursing facility, home health agency, counselor, educational consultant, psychiatrist, psychologist, or other licensed health care professional, caregiver or other Person who is in a position to make or influence referrals to or otherwise generate business for Seller to provide goods or services or engage in any other venture or activity.

(d) No Affiliate of Seller directly or indirectly: (i) provides any services to Seller, or is a lessor, lessee or supplier to Seller; (ii) has any cause of action or other claim whatsoever against or, except as set forth on Schedule 4.17(d), owes any amount to, or is owed any amount by, Seller, except for claims and amounts owed in the ordinary course of business, such as for expense advances or unreimbursed expenses, accrued vacation pay and accrued benefits under Benefit Plans; (iii) has any interest in or owns property or rights used in the operation of the Business (including any Purchased Asset); (iv) is a party to any Contract relating to the operation of the Business (other than compensation and/or employee benefits payable in the ordinary course of business), or the Purchased Assets; or (v) received from or furnished to Seller any goods or services without adequate consideration.

Section 4.18 **FDA Compliance**(a) .

(a) Without limiting the representations and warranties set forth in Section 4.16 and Section 4.17, Seller possesses all Permits required by the FDA or any other Governmental Authority engaged in the regulation of drugs, pharmaceuticals, medical devices or biohazardous materials. Seller has not received any notice of Proceedings relating to the suspension, modification, revocation or cancellation of any such Permit. Neither Seller nor any of its officers, employees or agents has been convicted of any crime or engaged in any conduct that has previously caused or would reasonably be expected to result in (i) disqualification or debarment by the FDA under 21 U.S.C. Sections 335(a) or (b), or any similar law, rule or regulation of any other Governmental Authorities, (ii) debarment, suspension, or exclusion under any Federal healthcare programs or by the General Services Administration, or (iii) exclusion under 42 U.S.C. Section 1320a-7 or any similar law, rule or regulation of any Governmental Authority. Neither Seller nor any of its officers, employees, or, to Seller's Knowledge, any of its contractors or agents is the subject of any pending or threatened investigation by FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" policy as stated at 56 Fed. Reg. 46191 (September 10, 1991) (the "***FDA Application Integrity Policy***") and any amendments thereto, or by any other similar Governmental Authority pursuant to any similar policy. Neither Seller nor any of its officers, employees, contractors, and agents has committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for FDA to invoke the FDA Application Integrity Policy or for any similar Governmental Authority to invoke a similar policy. Neither Seller nor any of its officers, employees, agents, or to the Knowledge of Seller, any of its contractors has made any materially false statements on, or material omissions from, any notifications, applications, approvals, reports and other submissions to FDA or any similar Governmental Authority.

(b) For the past ten (10) years, Seller is and has been in compliance with all Laws administered or issued by the FDA or any similar Governmental Authority, including the Federal Food, Drug, and Cosmetic Act and all other Laws regarding developing, testing, manufacturing, marketing, distributing or promoting the products of Seller, or complaint handling or adverse event reporting.

Section 4.19 **Privacy Matters**(c) . Seller and, to the Knowledge of Seller, all third parties acting on behalf of Seller comply, and have complied with all: (a) Laws (including, without limitation, Texas Medical Records Privacy Act and the Texas Identity Theft Enforcement and Protection Act); (b) privacy policies of Seller; (c) obligations contained within Contracts to which Seller is or was a party or by which Seller is or was bound; (d) rules of applicable self-regulatory or other industry organizations by which Seller is or was bound; (e) fiduciary obligations; and (f) published industry standards (to which published industry standards Seller has committed publicly or contractually to adhere, or has stated that it will adhere to in any internal policy document) (collectively, "***Privacy Laws and Requirements***"), relating to (i) the privacy of Seller's donors and customers; (ii) marketing to, or other communications with, consumers or to consumer protection; and (iii) the collection, use, storage, retention, disclosure, security, transfer, disposal, interception, or any other processing of any Personal Data or donor or customer data by or for Seller or by third parties having authorized access to any Personal Data or donor or customer data maintained by or for Seller. The execution, delivery and performance by Seller of this Agreement, and the transfer of all Personal Data and donor or customer data maintained by or for Seller to Buyer, are and will be compliant with all Privacy Laws and Requirements. There is not and has not been any complaint to, or any Proceeding or claim against, Seller by any private party (including any donor), the Federal Trade Commission, any state attorney general or similar state official or any other Governmental Authority, in each case, with respect to the collection, use, retention, disclosure, transfer, interception, storage, disposal, or other processing of Personal Data or donor or customer data. To the Knowledge of Seller, Seller has not suffered or experienced any privacy or security breaches.

Section 4.20 **Federal Healthcare Program Participation and Third Party Payors**. Seller does not participate and has not participated as a provider in any of the Medicare, Medicaid or TRICARE programs. Seller is not, and has not been, party to any Contract with, and does not bill for payment or reimbursement, any third-party payors, including private insurance companies.

Section 4.21 **Controlled Substances**. None of Seller's employees, or Persons who provide professional services under Contracts with Seller, has engaged in any activities within the scope of their services in connection with the Business that are prohibited under the federal Controlled Substances Act (21 U.S.C. § 801 *et seq*.) or the regulations promulgated pursuant to such statute or any related state or local statutes or regulations concerning the dispensing and sale of controlled substances.

Section 4.22 **Taxes**.

(a) Seller has filed or caused to be filed in a timely manner (taking into account all extensions of due dates) with the appropriate Governmental Authorities all Tax Returns (including information returns) that are required to be filed by or on behalf of Seller. All such Tax Returns are correct and complete in all material respects. All Taxes owed by Seller (whether or not shown on any Tax Return and whether or not any Tax Return was required) have been paid in full. No claim has been made by a taxing authority in a jurisdiction where Seller does not file Tax Returns that Seller is or may be subject to taxation by that jurisdiction. There are no Encumbrances on any of the assets of Seller that arose in connection with any failure (or alleged failure) to pay any Tax, except for Permitted Encumbrances.

(b) Seller has, within the time and manner prescribed by Law, withheld and paid all Taxes required to have been withheld and paid in connection with any amounts paid or owing to any employee, independent contractor, creditor, stockholder, or other third party.

(c) No deficiencies for Seller's Taxes have been claimed, proposed or assessed in writing by any Governmental Authority. There are no pending or, to the Knowledge of Seller, threatened Proceeding for or relating to Seller's Taxes. Seller has delivered to Buyer correct and complete copies of all Tax Returns filed by or with respect to Seller, examination reports and statements of deficiencies received by Seller or assessed against or agreed to by Seller, all since January 1, 2017.

(d) Seller has not waived any statute of limitations in respect of Seller's Taxes or agreed to any extension of time with respect to a Tax assessment or deficiency.

(e) There are no Tax-sharing or allocation agreements or similar arrangements (including indemnity arrangements) with respect to or involving Seller, and, after the Closing Date, Seller will not be bound by any such Tax-sharing or allocation agreements or similar arrangements entered into prior to the Closing or have any liability thereunder for amounts due in respect of periods prior to the Closing Date.

(f) Seller has not been a member of an affiliated group filing a consolidated federal (or combined state) income Tax Return. Seller does not have any liability for the Taxes of any Person (i) under Treasury Regulation Section 1.1502-6 (or any similar provision of state, local or foreign law), (ii) as a transferee or successor, (iii) by Contract, or (iv) otherwise.

(g) Seller is not a "foreign person" as that term is used in Treasury Regulations Section 1.1445-2.

(h) Seller has not entered into any transaction identified as a "reportable transaction" for purposes of Treasury regulations Sections 301.6011-4(b).

Section 4.23 **Employee Benefit Plans and Related Matters**.

(a) Schedule 4.23 sets forth a true, complete and correct list of all Benefit Plans. Seller has made available to Buyer, with respect to each Benefit Plan, true, correct and complete copies of the following documents, as applicable: (i) the Benefit Plan documents and all amendments (or, in the case of any unwritten Benefit Plan, written descriptions, including the material terms, thereof), (ii) any related trust agreements, insurance contracts or other funding instruments, (iii) the most recent IRS determination letter (if applicable), (iv) the three most recent annual reports, or such similar reports, statements, information returns or material correspondence required to be filed with or delivered to any Governmental Authority (including reports filed on Form 5500 with accompanying schedules and attachments), (v) the most recent summary plan description and summary of material modifications concerning the extent of the benefits provided under each Benefit Plan, (vi) the two most recent actuarial valuations (if applicable), (vii) coverage and nondiscrimination testing reports and other similar compliance reports, and (viii) copies of all material notices, letters, or other correspondence from the Internal Revenue Service, Department of Labor, or other Governmental Authority relating to any Benefit Plan. Except as specifically provided in the foregoing documents made available to Buyer, there are no amendments to any Benefit Plan that have been adopted or approved, nor has Seller undertaken to make any such amendments or to adopt or approve any new Benefit Plan. Each Benefit Plan has been established, administered, funded and, to the extent applicable, the assets of such Benefit Plan have been invested in accordance with its terms. Seller, each Benefit Plan and PEO are, and have been, in compliance with applicable Law, including ERISA, the Code and the terms of any collective bargaining agreements or other labor union Contracts. All reports relating to each Benefit Plan required to be filed with any Governmental Authority have been timely filed, and all reports and information relating to each Benefit Plan required to be disclosed or provided to participants or their beneficiaries have been timely disclosed or provided. No Benefit Plan is the subject of an application or filing under, or is a participant in or considering being a participant in, an amnesty, voluntary compliance, self-correction, or similar program sponsored by any Governmental Authority (including the Employee Plans Compliance Resolution System, the Voluntary Fiduciary Correction Program, or the Delinquent Filers Voluntary Correction Program).

(b) No Benefit Plan is, and neither Seller nor any ERISA Affiliate has sponsored, maintained or contributed to (or been required to sponsor, maintain or contribute to), or has any actual or contingent Liability under, any employee benefit plan that is (i) a "defined benefit plan" (as defined in Section 3(35) of ERISA), (ii) otherwise a defined benefit pension plan or that provides for the payment of termination indemnities, or (iii) subject to Section 412 of the Code, Section 302 of ERISA and/or Title IV of ERISA. No Benefit Plan is, and neither Seller nor any ERISA Affiliate has sponsored, maintained or contributed to or been required to sponsor, maintain or contribute to, or has any actual or contingent Liability under, a multiemployer plan (as defined in Section 3(37) or Section 4001(a)(3) of ERISA) or a multiple employer welfare arrangement (as defined in Section 3 (40) of ERISA).

(c) Each Benefit Plan intended to be qualified under Section 401(a) of the Code has a current favorable determination letter (a true, correct and complete copy of which was made available to Buyer) as to its qualification or may rely on the IRS notification letter to the sponsor of any prototype plan used to document the terms of such Benefit Plan as to the tax-qualified status of such Benefit Plan. All contributions (including any employee salary reduction contributions) or other amount payable (including premiums payable with respect to insurance policies funding any Benefit Plan) by Seller or PEO with respect to any Benefit Plan or required by applicable Law or any Contract have been timely made or paid in full or, to the extent not required to be made or paid on or before the date hereof, have been fully reflected on the Financial Statements. Seller has not incurred, nor could be reasonably expected to incur, any unfunded Liabilities in relation to any Benefit Plan. Seller has complied with the continuation coverage provisions of COBRA and any applicable state statutes mandating health insurance continuation coverage for employees. Seller has made available to Buyer a list of all qualified beneficiaries (within the meaning of Code section 4980B(g)(1)) of Seller who are eligible for and/or have elected continuation coverage under COBRA as of the date of this Agreement. No Benefit Plan provides benefits, and there are no understandings, written or oral, with respect to the provision of welfare benefits, after termination of employment, except as required by Section 4980B(f) of the Code or any similar state statute or foreign Law. Seller and PEO have complied with and acted consistently with their obligations under the Affordable Care Act and the rules and regulations promulgated thereunder, including, without limitation, with respect to providing timely notice to employees, offering affordable, minimum value medical insurance coverage to substantially all of its full-time employees (within the meaning of Section 4980H of the Code) and otherwise in respect of the "Employer Shared Responsibility" provisions of Section 4980H of the Code, and nothing has occurred with respect to any Benefit Plan that has subjected, or could reasonably be expected to subject, the Seller or any ERISA Affiliate or, with respect to any period on or after the Closing Date, Buyer or any of its affiliates, to a Tax or penalty under Section 4980H of the Code. None of Seller or PEO has attempted to maintain the grandfathered health plan status under the Affordable Care Act of any Benefit Plan. Seller is and has been in compliance with its obligations under its agreements with PEO, and no circumstances exist that reasonably would or could limit the ability of Buyer or Seller to benefit from the full rights and protections available to Seller pursuant to any of its agreements with PEO.

(d) With respect to any Benefit Plan, (i) no Proceeding (other than routine claims for benefits in the ordinary course) is pending or, to the Knowledge of Seller, threatened; (ii) to the Knowledge of Seller, no facts or circumstances exist that could give rise to any such Proceeding; and (iii) no administrative investigation, audit or other administrative proceeding by any Governmental Authority is pending, in progress or, to the Knowledge of Seller, threatened.

(e) None of the execution and delivery of this Agreement or any of the other agreements contemplated hereby, or the consummation of any transaction contemplated herein or therein (alone or in combination with any other event), could (i) result in the payment to any present or former director, officer, employee or other service provider of any money or other consideration; (ii) accelerate, trigger, enhance or provide any other rights or benefits to any present or former director, officer, employee or other service provider; (iii) accelerate, increase or trigger any material obligation under any Benefit Plan; (iv) result in any breach or violation of, or default or funding obligation under, or limit Seller's right to amend, modify or terminate, any Benefit Plan; or (v) trigger the forgiveness of any indebtedness owed by any present or former director, officer, employee or other service provider to Seller.

(f) No deduction of any amount payable pursuant to the terms of the Benefit Plans has been disallowed or is subject to disallowance under applicable Law, including Section 280G of the Code. Each Benefit Plan that is a "nonqualified deferred compensation plan" within the meaning of Treasury Regulation 1.409A-1(a)(1) (a "***Nonqualified Deferred Compensation Plan***"): has been operated in compliance with Section 409A of the Code and the rules and regulations promulgated thereunder and has been in documentary compliance with Section 409A of the Code for the entire period during which Section 409A of the Code has applied to such Benefit Plan. The Seller does not have any obligation to gross up, indemnify or otherwise reimburse any individual for any additional tax or interest incurred by such individual pursuant to Section 409A of the Code.

Section 4.24 **Employees and Employee Relations**.

(a) There is no pending or, to the Knowledge of Seller, threatened employee strike, work stoppage or labor dispute against or involving the Business. To the Knowledge of Seller, no demand has been made for recognition by a labor organization by or with respect to any employees of Seller, no union organizing activities by or with respect to any employees of Seller are taking place, and none of the employees of Seller are represented by any labor union or organization. No collective bargaining agreement exists or is currently being negotiated by Seller, and there is no unfair practice claim against Seller pending before the National Labor Relations Board. There are no pending or, to the Knowledge of Seller, threatened demands, complaints, charges or litigation before any Governmental Authority regarding employment discrimination, harassment or retaliation, safety or working conditions, wage and hour claims, unemployment compensation claims, or workers' compensation claims or the like.

(b) Schedule 4.24 contains a list of all of the employees and consultants of Seller as of the date hereof (the "***Employees***"), their current salary, wage or hourly rates, bonus and other compensation, benefit arrangements, accrued sick days, vacation days and holidays, periods of service, departments and job titles, full-time or part-time status and leave status.

(c) Seller has complied, and is in compliance, with all Laws relating to employment, including (without limitation) employment discrimination, harassment and retaliation, safety and working conditions, wages and hours, unemployment compensation, workers compensation, whistleblowing, and similar Laws. Seller has properly classified all individuals it has designated as exempt from the wage and hour Laws and/or all individuals Seller treats as independent contractors.

Section 4.25 **Environmental Matters**.

(a) Seller is and has been in compliance with Environmental Laws, which compliance includes but is not limited to the possession by Seller of all Permits required under Environmental Laws relating to the Business, the Purchased Assets or other properties or facilities of Seller.

(b) Seller has not treated, stored, managed, disposed of, transported, handled, released, or used any Material of Environmental Concern except in the ordinary course of its business and in compliance in all material respects with all Environmental Laws.

(c) There are no Environmental Claims pending or to the Knowledge of Seller, threatened against Seller and Seller has received no such claims.

(d) Schedule 4.25(d) contains a complete and accurate list of all off-site treatment, storage, or disposal facilities or locations used by or on behalf of Seller, and to the Knowledge of Seller, none of these facilities or locations is or has been designated or proposed for designation as a Superfund sites under CERCLA, or any similar state list, and Seller has not received any request for information or notice it is or may be a potentially responsible party of potential Liabilities with respect to such off-site treatment, storage, or disposal facilities or locations.

(e) There are no and have not been any Material of Environmental Concern used, generated, treated, stored, transported, disposed of, handled or otherwise existing on, under or about any personal or real property owned, leased, operated or used by Seller, nor has there been any release of any Material of Environmental Concern therefrom, in violation of or which could be the basis of liability or obligation under Environmental Laws. No real property currently or formerly owned, operated or leased by Seller is or has been designated or proposed for designation as a Superfund site under CERCLA, or any similar state list.

(f) Seller has delivered to Buyer true and complete copies of all environmental reports and other investigations, studies, audits, tests, reviews or other analyses commenced or conducted by or on behalf of Seller (or by a third party of which Seller has knowledge) in relation to Seller or any real property presently or formerly owned, leased, used or operated by Seller (or its predecessors) that are in the possession, custody or control of Seller.

(g) Seller is not aware of and does not reasonably anticipate any condition, event or circumstance concerning the release or regulation of Materials of Environmental Concern that might, after the Closing Date, prevent, impede or materially increase the costs associated with the ownership, lease, operation, performance or use of the Business as currently conduct or of the Purchased Assets.

Section 4.26 **Medical Waste**. The operations and properties of Seller are and at all times have been in compliance with the Medical Waste Laws.

Section 4.27 **Bank Accounts**. Schedule 4.27 contains a complete and correct list of the names and locations of all banks in which Seller has accounts or safe deposit boxes, the names of all Persons authorized to draw thereon or to have access thereto, and the account number for each bank account of Seller.

Section 4.28 **Brokers**. No broker, investment banker, financial advisor or other similar Person is entitled to any broker's, finder's, financial advisor's or other similar fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of Seller.

Section 4.29 **Absence of Certain Changes**. Between the Balance Sheet Date and the date hereof, except as set forth on Schedule 4.29: (a) the Business has been conducted in the ordinary course of business consistent with past practice; (b) the Business has not suffered any theft, damage, destruction or casualty loss in excess of $5,000 in the aggregate to its assets, whether or not covered by insurance; (c) there have not been any Effects which, individually or in the aggregate, have constituted, constitute, or would reasonably be expected to constitute, a Material Adverse Effect, and (d) Seller has not taken any action, which, if taken after the date of this Agreement, would require the consent of Buyer under Section 6.2.

Section 4.30 **Related Party Transactions**. Except as set forth on Schedule 4.30, no officer, director, direct or indirect shareholder, or Affiliate of Seller or any individual in such officer's, director's, direct or indirect shareholder's or Affiliate's immediate family is a party to any transaction or agreement (other than employment agreements) with Seller or has any material interest in any material assets, properties or rights (including the Purchased Assets) that are required for or used by Seller or in connection with the conduct of the Business.

Section 4.31 **Anti-Money Laundering**. The Business, and the operations of Seller, are and have been conducted at all times in compliance with all anti-money laundering Laws and all applicable financial record keeping and reporting requirements, rules, regulations and guidelines applicable to Seller (collectively, "***Money Laundering Laws***") and no claim by or before any Governmental Authority involving Seller with respect to Money Laundering Laws is pending and, to the Knowledge of Seller, no such claims are threatened or contemplated.

Section 4.32 **OFAC**. Seller will not directly or indirectly use the proceeds derived from any of the transactions contemplated under this Agreement or otherwise make available the proceeds therefrom, to any Person, for the purpose of financing the activities of any Person in violation of sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department or any other applicable U.S. sanction Laws.

Section 4.33 **PPP Loan**. All information submitted to the PPP Lender by Seller in connection with Seller's application for its PPP Loan and its application for forgiveness, and any required supporting documentation, was true and correct in all material respects as of the date such information was provided to the PPP Lender. Seller has delivered to Buyer true, correct and complete copies of its applications for forgiveness of its PPP Loan (if any) and all material correspondence or communication from the PPP Lender or U.S. Small Business Administration with respect to its PPP Loan or its application for forgiveness (if any). As authorized by Section 1106 of the CARES Act, SBA has remitted to the "Lender of Record" (PPP Lender) all principal and interest due and payable by Seller on the PPP Loan, resulting in the PPP Loan being forgiven in full. Except for the PPP Loan, Seller has not applied for, received, claimed or invoked any tax deferral, tax credit, loan, grant or other benefit made available under the CARES Act, including but not limited to any other loan under the Paycheck Protection Program, any Economic Injury Disaster Loan or any Economic Injury Disaster Loan Emergency Advance.

ARTICLE V
REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller that the statements contained in this Article V are true and correct as of the date hereof and as of the Closing Date, except (i) for representations or warranties made with respect to a specified date (in which case the applicable representations or warranties shall be true and correct only as of such specified date) and (ii) as set forth in the Buyer Disclosure Schedules (the parts of which are numbered to correspond to the particular Section or subsection of this Agreement to which the information set forth in the Seller Disclosure Schedules relates):

Section 5.1 **Organization; Good Standing; Qualification**. Buyer is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware. Buyer has the requisite power and authority to enter into this Agreement and the other Transaction Documents to which it is a party, perform its obligations hereunder and thereunder, own, lease, and operate its properties and to conduct its businesses as currently conducted.

Section 5.2 **Consents; Absence of Conflicts With Other Agreements, Etc.** The execution, delivery and performance by Buyer of this Agreement and the other Transaction Documents to which Buyer is a party, and the consummation of the transactions contemplated hereby and thereby:

(a) are not in contravention of the terms of any of its governing documents;

(b) will neither constitute a violation of or a default under, or conflict with, any Law or any term or provision of any Contract to which Buyer is a party or by which Buyer is bound; and

(c) do not require Buyer to obtain any approval consent of, waiver or authorization from, exemption by, or give notice to or make any filing with any other Person.

Section 5.3 **Due Execution; Binding Agreement**. This Agreement and, when executed by Buyer, the other Transaction Documents to which Buyer is a party (a) have been or will be duly authorized by all limited liability company action on the part of Buyer and duly executed and delivered by Buyer and (b) assuming due authorization, execution and delivery by Seller, are or will constitute the valid and legally binding obligation of Buyer and will be enforceable against Buyer in accordance with the respective terms hereof or thereof, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general principles of equity (regardless of whether enforcement is sought in a proceeding at law or in equity).

Section 5.4 **Litigation**. There is no Proceeding pending or, to the knowledge of Buyer, threatened, against or affecting Buyer that has or would reasonably be expected to have a material adverse effect on Buyer's ability to execute this Agreement and the other Transaction Documents to which it is a party and to perform its obligations contemplated hereby or thereby or any aspect of the transactions contemplated hereby or thereby.

Section 5.5 **Brokers**. No broker, investment banker, financial advisor or other similar Person is entitled to any broker's, finder's, financial advisor's or other similar fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of Buyer.

ARTICLE VI
PRE-CLOSING AGREEMENTS AND COVENANTS

Section 6.1 **Affirmative Covenants of Seller**. From the date hereof until the earlier of the termination of this Agreement in accordance with its terms or the Closing Date, except as otherwise permitted or required by this Agreement or as otherwise consented to by Buyer, Seller will use its commercially reasonable efforts to:

(a) carry on the Business in the ordinary course of business consistent with past practice, preserve the Purchased Assets intact, maintain the Purchased Assets, and Seller's other properties in the same operating condition as they exist as of the date of this Agreement, and preserve its relationship with its employees, donors, insurers under Business Insurance Policies, and suppliers of goods, services and other material benefits and entitlements used in connection with conducting the Business, or owning or operating the Real Property and the other Purchased Assets;

(b) invoice its customers and diligently use its commercially reasonable efforts to collect accounts receivables;

(c) pay Taxes and other Liabilities when due;

(d) perform its obligations under all Material Contracts, and comply with all Laws affecting Seller;

(e) use its commercially reasonable efforts to keep in full force and effect all Permits necessary for the operation of the Business as currently conducted, or to own, lease, or operate the Purchased Assets as they are currently owned, leased or operated; and

(f) maintain in effect the Business Insurance Policies.

Section 6.2 **Negative Covenants of Seller**. From the date hereof until the earlier of the termination of this Agreement in accordance with its terms or the Closing Date, except as otherwise permitted or required by this Agreement or as otherwise consented to by Buyer in writing, Seller shall not:

(a) except as may relate to trade payables of Seller or the Business incurred in the ordinary course of business and the renewal of any insurance coverage of Seller, enter into, renew, amend, breach or terminate any Material Contract other than in the ordinary course of business and consistent with past practice;

(b) sell, dispose of, license, assign or transfer, in whole or in part, any asset of Seller, whether real or personal, tangible or intangible, except in the ordinary course of business and consistent with past practices;

(c) (i) grant (or commit to grant) any increase in the rate or terms of compensation (including incentive or bonus compensation) or benefits of any director, officer, employee or service provider of Seller, whether past or present, (ii) institute, adopt, modify or amend (or commit to institute, adopt, modify or amend) any compensation or Benefit Plan, policy, program or arrangement or collective bargaining agreement applicable to any such director, officer, employee or service provider, (iii) pay or agree to pay any pension, retirement allowance, severance, transaction, retention, change in control, incentive or other payment or benefit to any director, officer, employee or service provider of Seller, whether past or present, or (iv) take any action to accelerate, or that could reasonably be expected to result in the acceleration of, the time of payment or vesting of any rights, compensation, benefits or funding obligations under any Benefit Plan or otherwise;

(d) make or change any Tax election, change any accounting period, adopt or change any method of accounting, file any amended Tax Return, enter into any closing agreement, settle any Tax claim or assessment, surrender any right to claim a Tax refund, consent to any extension or waiver of the limitations period applicable to any Tax claim or assessment or take any other similar action related to Taxes;

(e) issue, sell or otherwise dispose of (or agree to issue, sell or dispose) any of the capital stock or equity interests of Seller, or grant (or agree to grant) any options, warrants or other rights to purchase or obtain (including upon conversion, exchange or exercise) any of the capital stock or equity interests of Seller;

(f) amend, renew or terminate any of its Material Contracts, or enter into any Material Contract or cause or suffer any acceleration of, or grant any waiver or give any consent or release with respect to, any Material Contract (or Contract that would constitute a Material Contract had it not been so accelerated, amended, terminated, waived or released), or enter into any other material transaction;

(g) acquire or agree to acquire, by merging or consolidating with, by purchasing an equity interest in or a portion of the assets of, or by any other manner, any Person or division thereof;

(h) acquire (whether by purchase or lease) or sell, assign, lease or otherwise transfer or dispose of, or agree to acquire (whether by purchase or lease) or to sell, assign, lease or otherwise transfer or dispose of, any property, equipment or other assets of Seller (including for the avoidance of doubt, the Purchased Assets), or otherwise make capital expenditures, in each case, in an aggregate amount in excess of $5,000;

(i) create, assume or permit to exist any new Encumbrance upon any of the Purchased Assets (other than Permitted Encumbrances), or otherwise incur any indebtedness for borrowed money, or guarantee the obligations of any other Person;

(j) increase (or agree to increase) compensation or benefits (including the granting of options or restricted stock or other direct or indirect remuneration) payable to or to become payable to, or make (or agree to make) any bonus payment to, any employee or agent of Seller, except in accordance with existing personnel policies or plans, or enter into any employment, severance or similar agreement with any such employee or agent;

(k) institute or settle any claim or lawsuit for an amount involving in excess of $5,000 in the aggregate or involving equitable or injunctive relief;

(l) file a petition in bankruptcy under any provisions of federal or state bankruptcy Law or consent to the filing of any bankruptcy petition any against Seller under any similar Law;

(m) waive, cancel, compromise or release any rights or claims of material value, whether or not in the ordinary course of business;

(n) change in any material respect its methods of accounting in effect on the Balance Sheet Date, except as required by changes in GAAP or regulatory accounting principles or applicable Law or as disclosed in the notes to the Financial Statements;

(o) enter into any transaction that is not in the ordinary course of business (other than this Agreement and the transactions contemplated by this Agreement), including any transfer of assets; or

(p) commit or agree, in writing or otherwise, to any of the foregoing, except as expressly contemplated by this Agreement.

Section 6.3 **Efforts to Close; Consents**. From the date hereof until the earlier of the termination of this Agreement in accordance with its terms or the Closing Date, except as otherwise specified herein, each Party shall use its commercially reasonable efforts to: (a) provide all notices required of any Governmental Authority to consummate the transactions contemplated hereby, (b) obtain all Permits (or exemptions therefrom) necessary or required to allow such Party to perform its obligations under this Agreement; (c) in respect of Seller, obtain all consents from all third parties to the Key Contracts in connection with the consummation of the transactions contemplated hereby and/or, at Buyer's election, cooperate with Buyer in securing a replacement contract for any Key Contract, and in respect of Buyer, reasonably cooperate with Seller in connection therewith (d) to the extent within such Party's control, cause all of the conditions to the consummation of the Closing to be fulfilled or otherwise satisfied by it, (e) keep the other party reasonably informed of any material communication received by such party from, or given by such party to, any Governmental Authority or any other Person (including relating to the Key Contracts), in connection with any consent or Proceeding, and (f) take all other actions and to do all other things necessary in order to consummate and make effective, as soon as reasonably practicable, the transactions contemplated by this Agreement; provided that, neither Party has any obligation to waive any rights to which it is entitled hereunder or under any other applicable Transaction Document.

Section 6.4 **No Solicitation of Other Bids**. Between the date hereof and the Closing Date, none of Seller, the Seller Shareholders, nor the Affiliates or Representatives of each of the foregoing (collectively, the "***No-Shop Restricted Parties***"), shall authorize or permit any Person to, directly or indirectly, (a) encourage, solicit, initiate or facilitate (including by way of providing to any Person, information regarding, or access to, Seller, its Business, the Purchased Assets or any of the No-Shop Restricted Parties) any Acquisition Proposal; (b) enter into discussions or negotiations with any Person concerning a possible Acquisition Proposal; or (c) enter into any agreements or other instruments (whether or not binding) regarding an Acquisition Proposal. For purposes hereof, "***Acquisition Proposal***" shall mean any proposal or offer from any Person (other than Buyer or any of its Affiliates) concerning (i) a merger, acquisition, asset purchase, consolidation, liquidation, recapitalization or other business combination transaction involving Seller or the Purchased Assets; (ii) the issuance or acquisition of capital stock of Seller; or (iii) the sale, lease, exchange or other disposition of any significant portion of the properties or assets of Seller.

Section 6.5 **Pre-Closing Access**. Subject to applicable Laws relating to the exchange of information, during the period from the date of this Agreement and continuing until the earlier of the termination of this Agreement and the Closing Date, Seller shall (a) give Buyer, its Affiliates and their respective authorized Representatives reasonable access, upon reasonable notice during normal business hours, to all books, records, personnel, the Purchased Assets and such other properties utilized by Seller in connection with the Business, (b) permit Buyer, its Affiliates and their respective authorized Representatives to make such reasonable inspections thereof as Buyer may request (such inspections may include Buyer environmental inspections) and (c) cause its personnel and accountants to furnish Buyer its Affiliates and their respective authorized Representatives with such financial and operating data and other information with respect to Seller, the Business and the Purchased Assets, as Buyer may from time to time reasonably request.

ARTICLE VII
CONDITIONS PRECEDENT

Section 7.1 **Mutual Conditions**. The obligations of each Party to consummate the transactions contemplated hereby shall be subject to the satisfaction, or waiver in whole or in part (by mutual agreement of the Parties), at or prior to the Closing, of the following conditions:

(a) **No Order or Prohibition**. No Governmental Authority shall have enacted, issued, promulgated, enforced or entered any Order which is then in effect and has the effect of prohibiting or making this Agreement, the Transaction Documents or any of the transactions contemplated hereby or thereby, illegal or limiting, restricting or prohibiting in any significant respect, Buyer or any of its Affiliates' ability to conduct and operate the Business or own, use and operate the Purchased Assets.

Section 7.2 **Buyer's Conditions**. The obligations of Buyer to consummate the transactions contemplated hereby shall be subject to the satisfaction at or prior to the Closing of the following conditions, any and all of which may be waived by Buyer in whole or in part:

(a) **Seller's Deliverables.** Seller shall have delivered to Buyer the agreements, documents and other items described in Section 3.2.

(b) **Consents and Approvals**. Seller shall have obtained and delivered to Buyer all approvals and consents of, and have given notice to and made all filings with the Governmental Authorities required of Seller and identified on Schedule 4.4. Seller shall have obtained all consents required under the Key Contracts for the consummation of the transactions contemplated hereby; provided, that, if the vendor under any Key Contract will not provide such consent, then, at the election of Buyer, it shall be a further condition to closing that Buyer shall have executed a replacement contract with such vendor on such terms and conditions as may be approved by Buyer.

(c) **Compliance with Agreement**. Each and all of the terms, covenants, agreements and conditions of this Agreement to be complied with or performed by Seller on or before the Closing Date pursuant to the terms hereof shall have been duly complied with and performed in all material respects.

(d) **Representations and Warranties**. The Seller Fundamental Representations shall be true and correct in all respects as of the signing date and as of the Closing Date as though made as of the Closing Date (except for representations and warranties which address matters only as of a specific date, which representations and warranties shall continue as of the Closing Date to be true and correct in all respects as of such specific date). The Seller Non-Fundamental Representations shall be true and correct in all material respects (without regard to any qualifications as to Material Adverse Effect, materiality or similar qualifications contained in such representations and warranties) as of the signing date and as of the Closing Date as though made as of the Closing Date (except for representations and warranties which address matters only as of a specific date, which representations and warranties shall continue as of the Closing Date to be true and correct in all material respects (without regard to any qualifications as to Material Adverse Effect, materiality or similar qualifications contained in such representations and warranties) as of such specific date).

(e) **No Material Adverse Effect**. Since the date of this Agreement, there shall not have occurred, or been discovered, any event, effect, occurrence, fact or state of facts, development, condition, circumstance, or change that has had, or would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

(f) **Title Policy**. Buyer shall have received an owner's title insurance policy with respect to the Real Property, issued by a nationally recognized title insurance company acceptable to Buyer, written as of the Closing Date, insuring Buyer in such amounts and together with such endorsements (which endorsements shall be at Buyer's expense), and otherwise in such form, as Buyer shall require. Such title insurance policy shall insure fee simple title to each Real Property, free and clear of all Encumbrances other than Permitted Encumbrances. Buyer shall have received an appropriately certified ALTA/NSPS Land Title Survey showing no Encumbrances other than the Permitted Encumbrances, and otherwise in form and substance satisfactory to Buyer, for the Real Property. Buyer and Seller shall each bear 50% of the costs of such owner's title insurance policy and endorsements and survey.

(g) **Release of Encumbrances**. All Encumbrances relating to the Purchased Assets shall have been released in full, other than Permitted Encumbrances, and Seller shall have delivered to Buyer written evidence, in form satisfactory to Buyer in its reasonable sole discretion, of the release of such Encumbrances.

(h) **Environmental Diligence**. Buyer has received the results of its environmental due diligence with respect to the Real Property and Buyer is satisfied with the results of such environmental due diligence, including, but not limited to, Buyer's satisfaction with the contents of any environmental investigations or reports prepared in connection with such due diligence.

(i) **Tax Exemption Certification**. Buyer and its ultimate parent company, Kamada, Ltd., has obtained certification that the transactions contemplated by this Agreement are exempt from taxation under Israeli Tax Laws.

Section 7.3 **Seller's Conditions**. The obligations of Seller to consummate the transactions contemplated hereby shall be subject to the satisfaction at or prior to the Closing of the following conditions, any and all of which may be waived by Seller in whole or in part:

(a) **Buyer's Deliverables.** Buyer shall have delivered to Seller the agreements, documents and other items described in Section 3.3.

(b) **Compliance with Agreement**. Each and all of the terms, covenants, agreements and conditions of this Agreement to be complied with or performed by Buyer on or before the Closing Date pursuant to the terms hereof shall have been duly complied with and performed in all material respects.

(c) **Representations and Warranties**. The Buyer Fundamental Representations shall be true and correct in all respects (without regard to any qualifications as to Material Adverse Effect, materiality or similar qualifications contained in such representations and warranties) as of the signing date and as of the Closing Date as though made as of the Closing Date (except for representations and warranties which address matters only as of a specific date, which such representations and warranties shall continue as of the Closing Date to be true and correct in all respects (without regard to any qualifications as to materiality, Material Adverse Effect, or similar qualifications contained in such representations and warranties) as of such specific date). All other representations and warranties of Buyer set forth in Article V shall be true and correct in all material respects (without regard to any qualifications as to Material Adverse Effect, materiality or similar qualifications contained in such representations and warranties) as of the signing date and as of the Closing Date as though made as of the Closing Date (except for representations and warranties which address matters only as of a specific date, which representations and warranties shall continue as of the Closing Date to be true and correct in all material respects (without regard to any qualifications as to Material Adverse Effect, materiality or similar qualifications contained in such representations and warranties) as of such specific date).

ARTICLE VIII
ADDITIONAL AGREEMENTS AND COVENANTS

Section 8.1 **Post-Closing Access to Information**. For a period of four years after the Closing, subject to customary confidentiality restrictions, the Parties will make available to one another upon written request such documents and information as may be available relating to Seller, the Business and the Purchased Assets for periods prior and subsequent to Closing to the extent reasonably necessary to facilitate concluding the transactions herein, contemplated, audits, compliance with governmental requirements and regulations and the prosecution or defense of claims.

Section 8.2 **Noncompetition Agreement**.

(a) In consideration for the benefits Seller and the Seller Shareholders will receive in connection with the transactions contemplated herein, which benefits Seller and each Seller Shareholder hereby acknowledges, and as further consideration for, and as a condition to, the transactions contemplated hereby, Seller and each Seller Shareholder covenants and agrees that for a period commencing as of the Closing Date and continuing thereafter for a period of five (5) years, neither Seller nor any Seller Shareholder will, anywhere within the Restricted Territory, directly or indirectly, (i) operate develop or own any interest (other than the ownership of less than 2% of the equity securities of a publicly traded company) in any business which has activities relating to the ownership of, the management or operation of, or consultation regarding a plasma, blood and blood products collection and processing operation and/or the sale of blood products or services (a "***Competing Business***"); (ii) consult with, advise (whether formally or informally) or be employed by, any business which directly or indirectly owns, manages or operates a Competing Business; (iii) interfere with, solicit, disrupt or attempt to disrupt any past present or prospective relationship, contractual or otherwise, between Seller, on one hand, and any donor, supplier, customer or employee of Seller, on the other hand; or (iv) solicit any past, present or prospective employee of Seller to leave his or her employment with Seller ((i)-(iv) above being collectively the "***Prohibited Activities***"). Seller and each Seller Shareholder acknowledges and agrees that the Restricted Territory and Prohibited Activities substantially cover the geography and activities that comprise the market in which Seller conducts the Business as of even date with this Agreement.

(b) Seller and each Seller Shareholder hereby acknowledges that its agreements not to engage in the Prohibited Activities for the period of time provided herein are manifestly reasonable upon their face and that they are reasonable as to time and no greater than is required for the reasonable protection of Buyer in light of the substantial harm that Buyer would suffer should Seller or any Seller Shareholder breach any of the provisions of this Section 8.2. Seller and each Seller Shareholder further agrees that the nature, kind and character of the Prohibited Activities are reasonably necessary to protect the interests of Buyer.

(c) If a judicial determination is made that any of the provisions of this Section 8.2 constitute an unreasonable or otherwise unenforceable restriction against Seller or any Seller Shareholder, the provisions of this Section 8.2 shall be rendered void only to the extent that such judicial determination finds such provisions to be unreasonable or otherwise unenforceable. Any judicial authority construing this Section 8.2 shall be empowered to sever any portion of the Restricted Territory or Prohibited Activities from the coverage of this agreement and to apply the provisions of this Section 8.2 to the remaining portion of the territory or the remaining activities not so severed by such judicial authority.

(d) Seller and each Seller Shareholder agrees that any violation of this Section 8.2 will result in irreparable injury to Buyer, that a remedy at law for any breach or threatened breach of the covenants contained herein will be inadequate and that in the event of any such breach, Buyer, in addition to any other remedies or damages available to Buyer at law or in equity, shall be entitled to seek temporary injunctive relief before trial from any court of competent jurisdiction as a matter of course and to seek permanent injunctive relief without the necessity of proving actual damages or securing or posting any bond.

Section 8.3 **Certain Tax Matters**.

(a) **Transfer Taxes**. All transfer, documentary, sales, use, stamp, registration and other such Taxes, and all conveyance fees, recording charges and other fees and charges (including any penalties and interest) incurred in connection with the consummation of the transactions contemplated by this Agreement ("***Transfer Taxes***") shall be paid by Seller. The party required by law to file a Tax Return with respect to such Transfer Taxes shall do so in the time and manner prescribed by law, and the non-filing party shall promptly reimburse the filing party for its share of any Transfer Taxes upon receipt of evidence reasonably satisfactory to the non-filing party of the amount of such Transfer Taxes.

(b) **Tax Clearance Certificates**. Seller shall notify all of the taxing authorities in the jurisdictions that impose Taxes on Seller or where Seller has a duty to file Tax Returns of the transactions contemplated by this Agreement in the form and manner required by such taxing authorities, if the failure to make such notifications or receive any available tax clearance certificate (a "***Tax Clearance Certificate***") could subject the Buyer to any Taxes of Seller. If any taxing authority asserts that Seller is liable for any Tax, Seller shall promptly pay any and all such amounts and shall provide evidence to the Buyer that such liabilities have been paid in full or otherwise satisfied.

(c) **Tax Claims**. Notwithstanding anything herein to the contrary, Buyer shall control the conduct and resolution of any Claim which involves the assertion of any claim or the commencement of any action, in respect of which an indemnity may be sought by a Buyer Indemnified Party pursuant to this Agreement (a "***Tax Claim***"); provided that Seller may participate in such proceedings at its own expense. Buyer and Seller agree to give prompt written notice to each other of the receipt of any written notice by any of them which involves a Tax Claim; provided, that the failure to give such notice shall not affect the indemnification provided hereunder.

(d) **Tax Cooperation**. Seller shall cooperate fully, as and to the extent reasonably requested by Buyer, in connection with (i) the preparation and filing of any Tax Return of Buyer, (ii) any Tax Claim, (iii) the procurement of Tax exemption certificates in connection with the Business; (iv) obtaining Tax Clearance Certificates and assuring the Buyer has no liability for state Taxes of Seller; and (v) any other matter under this Agreement relating to Taxes of the Company with respect to any Straddle Period. Such cooperation shall include the retention and, upon Buyer's request, the provision of records and information that are reasonably relevant to any such Tax matter and access to employees and representatives on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. Seller agrees to (x) retain all books and records relevant to Tax matters of Seller with respect to Pre-Closing Tax Periods until the expiration of the statute of limitations (and any extensions thereof) of the applicable Tax period, and (y) give Buyer reasonable written notice prior to destroying or discarding any such books and records and, if Buyer so requests upon such notice, the Seller shall allow Buyer to take possession of such books and records.

(e) **Straddle Period**. In the case of any Straddle Period, the amount of any Taxes based on or measured by income, receipts, sales, use or payroll of Seller for the Pre-Closing Tax Period shall be determined based on an interim closing of the books as of the close of business on the Closing Date, and the amount of other Taxes of Seller for a Straddle Period that relates to the Pre-Closing Tax Period shall be deemed to be the amount of such Tax for the entire taxable period multiplied by a fraction the numerator of which is the number of days in the taxable period ending on and including the Closing Date and the denominator of which is the number of days in such Straddle Period.

Section 8.4 **Employment Matters**.

(a) Effective as of the Closing Date, Buyer shall offer employment to all Employees who were employed or contracted by Seller as of immediately preceding the Closing Date (the "***Continuing Employees***"). Such offer of employment or to contract for service shall be on terms and conditions as determined by Buyer in its sole discretion. The Continuing Employees who accept employment or a contract for service with the Buyer are referred to as "***Hired Employees***." Seller will use all commercially reasonable efforts to assist the Buyer with the transition of all Hired Employees to Buyer. Notwithstanding the foregoing, nothing in this Agreement shall preclude Buyer or Seller from terminating the employment of any employee or discontinuing the services of an independent contractor or consultant at any time on or after the Closing.

(b) Seller shall be solely responsible, and Buyer shall have no obligations whatsoever for, any compensation or other amounts payable to any current or former employee, officer, director, independent contractor or consultant of Seller, including, without limitation, hourly pay, commission, bonus, salary, accrued vacation, fringe, pension or profit sharing benefits or severance pay for any period relating to the service with Seller at any time on or prior to the Closing Date (except as contemplated by the Transition Services Agreement) and Seller shall pay all such amounts to all entitled persons on or prior to the Closing Date.

(c) Seller shall remain solely responsible for the satisfaction of all claims for medical, dental, life insurance, health accident or disability benefits brought by or in respect of current or former employees, officers, directors, independent contractors or consultants of Seller or the spouses, dependents or beneficiaries thereof, which claims relate to events occurring on or prior to the Closing Date, whether such claims are reported before or after such date. Seller also shall remain solely responsible for all worker's compensation claims of any current or former employees, officers, directors, independent contractors or consultants of Seller which relate to events occurring on or prior to the Closing Date. Seller shall pay, or cause to be paid, all such amounts to the appropriate persons as and when due. Seller shall be solely responsible, and Buyer shall have no obligations whatsoever, for providing, or causing PEO to provide, continuation of coverage under a Benefit Plan pursuant to COBRA or similar state law to any Continuing Employees who do not become Hired Employees, including any obligation to provide notices thereunder.

(d) Within the 90 days prior to the Closing, Seller has not engaged, and will not engage, in a "plant closing" or "Mass layoff" as those terms are defined in the WARN Act or any state or local law similar in purpose. To the extent, if at all, the transactions contemplated by this Agreement would result in any obligation that notice shall be provided to employees pursuant to the WARN Act or any state or local law similar in purpose, such obligation shall be exclusively upon Seller to comply with and Buyer shall have no obligation to provide such notice.

(e) Notwithstanding anything to the contrary herein, nothing contained in this Section 8.4 shall (i) confer upon any Person (including any Continuing Employee) any rights, remedies or claims, including third party beneficiary rights or rights to employment, (ii) obligate Buyer or any of its Affiliates to maintain any particular compensation or benefit plan, policy, Contract, program or arrangement or (iii) be considered to be an amendment of any Benefit Plan.

Section 8.5 **CHOW**. Each Party shall reasonably cooperate with the other Party in seeking to provide all such notices or obtain all such Permits and consents. Seller will cooperate with Buyer for state or Federal required change of ownership application processes ("***CHOW***"), including, but not limited to, providing access to records, premises and personnel for inspections that may be required for the CHOW.

Section 8.6 **Inventory other than Acquired Inventory**. After Closing, Buyer will, at its sole cost and expense subject to the offset from the Purchase Price of the Destruction Costs, dispose of all Inventory other than the Acquired Inventory.

Section 8.7 **Accounts Receivable**. From and after the Closing, if Seller or any of its Affiliates receives or collects any funds relating to any accounts receivable of Buyer or any other Purchased Asset or any other funds belonging to Buyer, Seller or its Affiliate shall remit such funds to Buyer within three Business Days after its receipt thereof.

Section 8.8 **Further Assurances**. Following the Closing, each of the Parties shall, and shall cause their respective Affiliates to, execute and deliver such additional documents, instruments, conveyances and assurances and take such further actions as may be reasonably required to carry out the provisions hereof and give effect to the transactions contemplated by this Agreement and the Transaction Documents.

ARTICLE IX
INDEMNIFICATION

Section 9.1 **Indemnification by Seller**. Subject to and to the extent provided in this Article IX, Seller Indemnifying Parties shall (jointly and severally) indemnify and hold harmless Buyer and its officers, directors, members, shareholders, partners, employees, agents, Affiliates, and each of the heirs, executors, successors and assigns of any of the foregoing (collectively, the "***Buyer Indemnified Parties***", each a "***Buyer Indemnified Party***") from and against any and all Losses incurred by any Buyer Indemnified Party, based upon, in connection with, as a result of, relating to or arising from:

(a) any breach of, or inaccuracy in, any representation or warranty of Seller made herein or in any other Transaction Document (it being understood that for purposes of determining the existence of a breach of, or inaccuracy in, any such representation or warranty, as well as the quantification of any Loss arising out of any such breach or inaccuracy, no effect shall be given to any limitations or qualifications as to materiality, Material Adverse Effect or similar limitations);

(b) any breach, non-compliance or failure to perform any covenants or agreements of Seller; and

(c) any Excluded Asset or any Excluded Liability.

Section 9.2 **Indemnification by Buyer**. Subject to and to the extent provided in this Article IX, Buyer shall indemnify and hold harmless Seller and its officers, directors, managers, members, employees, agents and Affiliates (each a "***Seller Indemnified Party***") from and against any Losses incurred or suffered by any of the Seller Indemnified Parties as a result of or arising from:

(a) any breach of, or inaccuracy in, any representation or warranty made by Buyer herein or in any Transaction Document (it being understood that for purposes of determining the existence of a breach of, or inaccuracy in, any such representation or warranty, as well as the quantification of any Loss arising out of any such breach or inaccuracy, no effect shall be given to any limitations or qualifications as to materiality, Material Adverse Effect or similar limitations);

(b) any breach, non-compliance or failure to perform any covenant or agreement required to be performed by Buyer pursuant to this Agreement; and

(c) subject to Seller Indemnifying Parties' obligations under Section 9.1, any Assumed Liability.

Section 9.3 **Certain Limitations.**

(a) Seller Indemnifying Parties shall not be liable to the Buyer Indemnified Parties for indemnification under Section 9.1(a):

(i) until the aggregate amount of all Losses in respect of any Claims for indemnification under Section 9.1(a) exceeds Seven Thousand Five Hundred Dollars ($7,500.00) (the "***Basket Amount***"), in which event Seller Indemnifying Parties shall be required to pay and be liable for all such Losses, including the Basket Amount; and

(ii) to the extent the aggregate amount of all Losses in respect of Claims for indemnification under Section 9.1(a) has exceeded Two Hundred Fifty Thousand Dollars ($250,000.00) of the Purchase Price (the "***Maximum Amount***").

(b) Buyer shall not be liable to the Seller Indemnified Parties for indemnification under Section 9.2(a):

(ii) until the aggregate amount of all Losses in respect of any Claims for indemnification under Section 9.2(a) exceeds the Basket Amount, in which event Buyer shall be required to pay and be liable for all such Losses, including the Basket Amount;

(iii) to the extent the aggregate amount of all Losses in respect of Claims for indemnification under Section 9.2(a) has exceeded the Maximum Amount.

Notwithstanding the foregoing, the limitations set forth in this Section 9.3 shall not apply in the event of: (w) any indemnification pursuant to Section 9.1 (b), Section 9.1(c), Section 9.2(b), Section 9.2(c), (x) breach of any Seller Fundamental Representation, (y) any breach of any Buyer Fundamental Representation; (z) fraud or intentional misrepresentation.

Section 9.4 **Survival/Indemnity Period**.

(a) The representations, warranties, the covenants or agreements of Buyer and Seller set forth herein shall survive the Closing and, specifically:

(i) the Seller Fundamental Representations and Buyer Fundamental Representations shall survive for the longest permitted applicable statute of limitations applicable under applicable law;

(ii) the Seller Non-Fundamental Representations shall survive for a period of 24 months after the Closing Date;

(iii) Buyer's representations and warranties under Article V of this Agreement (other than Buyer Fundamental Representations) shall survive for a period of 24 months after the Closing Date;

(iv) the agreements and covenants of Seller or Buyer under this Agreement shall survive until the later of (A) the date of full and final performance, or (B) the longest permitted applicable statute of limitation under applicable law.

(b) And any claim by an Indemnitee against an Indemnitor in respect of any of the foregoing representations and warranties must be brought, if at all, during the applicable survival period set forth in Section 9.4(a).

(c) Notwithstanding anything herein to the contrary, if written notice of a Claim has been given in accordance with Section 9.5 by an Indemnitee to an Indemnitor prior to the expiration of the applicable representations and warranties, then the relevant representations and warranties shall survive as to such claim until such claim has been finally resolved.

Section 9.5 **Notice and Procedure**.

(a) Any Person seeking indemnity under any provision of this Agreement (the "***Indemnitee***") shall promptly notify in writing (and in any event no later than thirty (30) calendar days after the Indemnitee determines that it is entitled to make a claim under this Article IX) the Party from whom indemnity is sought (the "***Indemnitor***") as to (i) the nature of any claims (including any third party claims) in reasonable detail, and/or Losses asserted by or against the Indemnitee for which the Indemnitee intends to seek indemnity hereunder ("***Claims***") and (ii) if applicable, the commencement of any suit or proceeding brought (including by any third parties) to enforce any Claims. The Indemnitor shall, within fifteen (15) days of receipt of the applicable notice of claim for indemnification from the Indemnitee, notify the Indemnitee whether Indemnitor will assume the defense of any such suit or other proceeding. If Indemnitor assumes the defense of such suit or proceeding, the Indemnitee shall reasonably cooperate, at the Indemnitor's sole cost and expense, and shall be entitled reasonably to consult with the Indemnitor with respect to such defense. If Indemnitor fails to timely deliver notice of its intent to assume the defense of the such suit or proceeding or if the defendants in any such suit or proceeding include both the Indemnitor and the Indemnitee and the Indemnitee has reasonably concluded that there may be a conflict of interest between the positions of the Indemnitor and the Indemnitee in conducting the defense of any such action or that there may be legal defenses available to it that are different from or additional to those available to the Indemnitor, the Indemnitee shall have the right to select separate counsel to assume such defense and to otherwise participate in the defense of such action on behalf of such Indemnitee, in which case the reasonable fees and expenses of such counsel shall be at the expense of the Indemnitor. The Indemnitor shall not, without the written consent of the Indemnitee, which consent shall not be unreasonably withheld (A) settle or compromise any claim or consent to the entry of any judgment that provides for relief other than the payment of monetary damages, or (B) settle or compromise any claim or consent to the entry of any judgment that does not include, as an unconditional term thereof, the giving by the claimant to the Indemnitee of a release from all Liability in respect of such claim.

(b) The Indemnitee shall assist and reasonably cooperate with the Indemnitor in the conduct of litigation, the making of settlements and the enforcement of any right of contribution to which the Indemnitee may be entitled from any Person in connection with the subject matter of any litigation subject to indemnification hereunder. In addition, the Indemnitee shall, upon the reasonable request by the Indemnitor or counsel selected by the Indemnitor, attend hearings and trials, assist in the securing and giving of evidence, assist in obtaining the presence or cooperation of witnesses, make available its own personnel, and effect settlements; and shall use commercially reasonable efforts take such actions as may be reasonably necessary and appropriate in connection with such litigation. With respect to any suit or proceeding for which the Indemnitor has assumed the defense thereof, the Indemnitee shall have the right to join in the defense of such litigation or claim at such Indemnitee's own cost and expense, and, if the Indemnitee agrees in writing to be bound by and promptly to pay the full amount of any final judgment from which no further appeal may be taken, without recourse against Indemnitor, and if the Indemnitor is reasonably assured of the Indemnitee's ability to satisfy such agreement, then, at the option of the Indemnitee, such Indemnitee may take over the defense of such litigation or claim.

Section 9.6 **Payment of Claims; Offset**. In the event that there is any amount due and payable by any Seller Indemnifying Party to any Buyer Indemnified Party pursuant to this Agreement (an "***Indemnification Payment***"), then, in addition to other remedies available to Buyer, Buyer shall be entitled to offset against the Holdback Amount the amount of such Indemnification Payment, and the Holdback Amount due and payable to Seller pursuant to Section 2.5(b) shall be reduced by the amount of such Indemnification Payment.

Section 9.7 **Tax Treatment of Indemnity Payment**. All Indemnification Payments made by Seller under this Agreement shall be deemed adjustments to the Purchase Price, for Tax purposes.

ARTICLE X
TERMINATION

Section 10.1 **Termination Events**. This Agreement may be terminated at any time prior to Closing by written notice by (or on behalf of a Party) to the other Party upon the occurrence of any of the following:

(a) by mutual agreement of Buyer and Seller (expressed in writing);

(b) by either Buyer or Seller, if any permanent injunction, or Order of any court of competent jurisdiction or other Governmental Authority is issued and becomes final and non-appealable or any new Law or change to existing Law is enacted, in either case, permanently restraining, enjoining or otherwise preventing the consummation of the transactions contemplated hereby;

(c) by either Buyer or Seller, if Closing shall not have occurred on or prior to June 30, 2021 (the "***Outside Date***"); provided, however, that the right to terminate this Agreement under this Section 10.1(c) shall not be available to any Party whose breach (or, as applicable, whose Affiliate's breach) of its representations and warranties in this Agreement or whose failure (or, as applicable, whose Affiliate's failure) to perform any of its covenants and agreements under this Agreement shall have been the cause of the failure of the Closing to occur on or before such date;

(d) by Buyer, upon a breach in any material respect of any covenant, representation or warranty of Seller set forth herein shall have been breached or shall have been or become untrue, and (i) which breach has not been cured by Seller within thirty (30) calendar days (or such lesser number of calendar days remaining prior to the occurrence of the Outside Date), (ii) cannot be cured prior to the occurrence of the Outside Date, or (iii) would, if not cured by the applicable time period in the foregoing clauses (i) or (ii), result in the failure to satisfy the conditions set forth in Section 7.2;

(e) by Seller, upon a breach in any material respect of any covenant or agreement on the part of Buyer set forth in this Agreement, or if any representation or warranty of Buyer shall have been breached or shall have been or become untrue (i) which breach has not been cured by Buyer within thirty (30) calendar days (or such lesser number of calendar days remaining prior to the occurrence of the Outside Date), (ii) cannot be cured prior to the occurrence of the Outside Date, or (iii) would, if not cured by the applicable time period in the foregoing clauses (i) or (ii), result in the failure to satisfy the conditions set forth in Section 7.3.

Section 10.2 **Effect of Termination**. In the event of a termination of this Agreement pursuant to Section 10.1, all obligations of the Parties hereto shall terminate except the obligations or covenants set forth in Section 11.3, Section 11.4, Section 11.5, Section 11.6, Section 11.7, Section 11.8, and Section 11.9. Termination of this Agreement by a Party shall not preclude any Party from seeking remedies related to the intentional breach of any provision of this Agreement or fraud.

ARTICLE XI
GENERAL

Section 11.1 **Notice**. Any notice, demand or communication required, permitted, or desired to be given hereunder shall be deemed effectively given (a) as of the date of transmission when sent by e-mail to the applicable e-mail address indicated below, or (b) when personally delivered or (c) when received by overnight courier, addressed as follows:

To Seller:	Blood and Plasma Research, Inc. 4717 Valero Court Laredo, Texas 78046 Attn: Shelly Kerr
With a copy to:	Germer PLLC 550 Fannin, Suite 400 Beaumont, Texas 7770 Attn: Charles W. Goehringer, Jr. (cwgoehringer@germer.com)
To Buyer:	Kamada Plasma, LLC c/o Kamada Ltd. 2 Holzman St, Science Park, P.O Box 4081, Rehovot 7670402, Israel Attn: Amir London (Chief Executive Officer) Yifat Philip (General Counsel) (yifatp@kamada.com)

With a copy to: Jackson Walker L.L.P.
1401 McKinney Street, Suite 1900
Houston, Texas 77010
Attn: Marisela Peå Gonzalez (mgonzalez@jw.com)
Virginia Mimmack (vmimmack@jw.com)

or (d) to such other address, and to the attention of such other Person as any Party may designate in writing. Notice given by a Party's counsel shall be considered notice given by that Party.

Section 11.2 **Confidentiality; Public Announcement**.

(a) From and after the Closing, Seller shall, and shall cause its Affiliates to, hold, and shall use its reasonable best efforts to cause its or their respective Representatives to hold, in confidence any and all information, whether written or oral, concerning the Business or the Purchased Assets, and deliver promptly to Buyer, at Buyer's request, all such information (and all copies thereof in whatever form or medium) in Seller's possession or under Seller's control; provided that this provision shall not apply to information that Seller can show (i) is generally available to and known by the public through no act or omission of Seller, any of its Affiliates or their respective Representatives; or (ii) is lawfully acquired by Seller, any of its Affiliates or their respective Representatives from and after the Closing from sources which are not prohibited from disclosing such information by a legal, contractual or fiduciary obligation. If Seller or any of its Affiliates or their respective Representatives are compelled to disclose any information by judicial or administrative process or by other requirements of Law, Seller shall promptly notify Buyer in writing and shall disclose only that portion of such information which Seller is advised by its counsel in writing is legally required to be disclosed, provided that Seller shall use reasonable best efforts to obtain an appropriate protective order or other reasonable assurance that confidential treatment will be accorded such information.

(b) Neither Seller nor Buyer shall issue any press release or other public announcement concerning this Agreement or the transactions contemplated by this Agreement without the prior approval of the other Party. Notwithstanding the foregoing, either Seller or Buyer may issue a press release or other public announcement concerning the transactions contemplated by this Agreement to the extent required by applicable Law or to comply with accounting or other disclosure obligations.

Section 11.3 **Cost of Transaction**. Except as otherwise provided herein, (a) Seller shall pay all costs and premiums associated with expenses and disbursements of Seller and its agents, representatives, accountants and counsel incurred in connection with the subject matter hereof and any amendments hereto and (b) Buyer shall pay the fees, expenses and disbursements of Buyer and its agents, representatives, accountants and counsel incurred in connection with the subject matter hereof and any amendments hereto.

Section 11.4 **Governing Law; Submission to Jurisdiction; Waiver of Jury Trial**.

(a) The Parties agree that this Agreement shall be governed by and interpreted, construed and enforced in accordance with the laws of the State of Texas, excluding any conflict-of-laws rule or principle that might refer the governance or the interpretation, construction or enforcement of this Agreement to the laws of another jurisdiction. **BUYER AND SELLER HEREBY WAIVE THE RIGHT TO A TRIAL BY JURY, FROM WHATEVER SOURCE ARISING, IN CONNECTION WITH ANY PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.**

(b) Each of the Parties irrevocably agrees that any legal action or proceeding with respect to this Agreement or for recognition and enforcement of any judgment in respect hereof shall be brought and determined in the United States Federal Courts for the Eastern District of Texas, or if such legal action or proceeding may not be brought in such court for jurisdictional purposes, in the state courts of Texas situated in Jefferson County, Texas. Each of the Parties hereby (i) irrevocably submits with regard to any such action or proceeding to the exclusive personal jurisdiction of the aforesaid courts in the event any dispute arises out of this Agreement or any transaction contemplated by this Agreement and waives the defense of sovereign immunity, (ii) agrees that it shall not attempt to deny or defeat such personal jurisdiction by motion or other request for leave from any such court or that such action is brought in an inconvenient forum and (iii) agrees that it shall not bring any action relating to this Agreement or any transaction contemplated by this Agreement in any court other than any Texas state or federal court sitting in Texas.

Section 11.5 **Benefit/Assignment**. This Agreement shall inure to the benefit of and be binding upon the Parties and their respective successors and assigns and no others. Neither Party may assign any of its rights or delegate any of its obligations hereunder without the prior written consent of the other Party; provided, however, that, without the prior written consent of Seller, Buyer shall be permitted to assign in whole, or in part, its rights and obligations under this Agreement to one or more of its Affiliates (in which case Buyer shall nonetheless remain responsible to Seller for the performance of all of its obligations hereunder). Any purported assignment or delegation in violation of this Section 11.5 shall be null and void. No assignment or delegation shall relieve the assigning or delegating party of any of its obligations hereunder.

Section 11.6 **Waiver of Breach**. The waiver by either Party of a breach or violation of any provision of this Agreement shall not operate as, or be construed to constitute, a waiver of any subsequent breach of the same or another provision hereof.

Section 11.7 **Severability**. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law: (a) such provision will be fully severable; (b) this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof; (c) the remaining provisions of this Agreement will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom; and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms (including duration, area or amount) to such illegal, invalid or unenforceable provision as may be possible.

Section 11.8 **Entire Agreement/Amendment; Counterparts**. This Agreement, the other Transaction Documents, and all of the Exhibits and the Schedules hereto and thereto, constitute the entire agreement between or among the Parties with respect to the subject matter hereof, supersede all previous agreements, contracts and understandings. No amendments, modifications or changes in or to this Agreement shall be effective unless and until made in writing and signed by each of the Parties. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and all of which together shall constitute but one and the same instrument. A signed copy of this Agreement delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement. A ".pdf" signature page delivered by electronic mail shall be as acceptable as an original.

Section 11.9 **No Third Party Beneficiaries**. Except as contemplated under Article IX in respect of Buyer Indemnified Parties and Seller Indemnified Parties, the terms and provisions of this Agreement are intended solely for the benefit of the Parties and their respective successors or permitted assigns, and this Agreement does not, and shall not be construed to, confer third-party beneficiary rights upon any other Person.

Section 11.10 **Specific Performance**. The Parties agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with the terms hereof and that the Parties shall be entitled to specific performance of the terms hereof, in addition to any other remedy to which they are entitled at law or in equity.

Section 11.11 **Time of the Essence**. With regard to all dates and time periods set forth or referred to in this Agreement, time is of the essence.

SIGNATURES APPEAR ON THE FOLLOWING PAGE

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their authorized officers, all as of the date and year first above written.

SELLER:
BLOOD AND PLASMA RESEARCH, INC.

By: _____
Name: _____
Title: _____

BUYER:
KAMADA PLASMA, LLC

By: _____
Amir London, Manager

By: _____
Chaime Orlev, Manager

IN WITNESS WHEREOF, the Seller Shareholders hereby execute this Agreement for purposes of agreeing to their obligations hereunder, all as of the date and year first above written.

_____
KRISTI LOVELADY

_____
SHELLY KERR

_____
RAYANN ST. PETER WALDRON

Exhibit A
Form of Consulting Agreement of Kristi Lovelady

Exhibit B
Employment Agreement of Dan Browning

Exhibit C
Form of Jean Browning

Exhibit D
Form of Bill of Sale

Exhibit E
Form of Assignment and Assumption Agreement

Exhibit F
Form of Intellectual Property Assignment

Exhibit G
Form of Deed

Exhibit H
Form of Transition Services Agreement

Exhibit 8.1

SIGNIFICANT SUBSIDIARIES

Our significant subsidiaries are set forth below, all of which are either 100% owned by us or controlled by us.

Legal Name	Jurisdiction
Kamada Biopharma Limited	England and Wales
Kamada Inc.	Delaware
Kamada Plasma LLC	Delaware (wholly owned by Kamada Inc)
Kamada Assets (2001) Ltd.	Israel
Kamada Ireland Limited	Ireland

Exhibit 12.1

I, Amir London, certify that:

1. I have reviewed this annual report on Form 20-F of Kamada Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: February 24, 2021

/s/ Amir London
Amir London
Chief Executive Officer

Exhibit 12.2

I, Chaime Orlev, certify that:

1. I have reviewed this annual report on Form 20-F of Kamada Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: February 24, 2021

/s/ Chaime Orlev
Chaime Orlev
Chief Financial Officer

Exhibit 13.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Kamada Ltd. (the "Company") on Form 20-F for the period ended December 31, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, Amir London, Chief Executive Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 24, 2021

/s/ Amir London
Amir London
Chief Executive Officer

In connection with the Annual Report of Kamada Ltd. (the "Company") on Form 20-F for the period ended December 31, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, Chaime Orlev, Chief Financial Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 24, 2021

/s/ Chaime Orlev
Chaime Orlev
Chief Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 (File Nos 333-192720, 333-207933, 333-215983, 333-222891 and 333-233267) of Kamada Ltd. (the "Company") of our reports dated February 24, 2021, with respect to the Company's consolidated financial statements and the effectiveness of internal control over financial reporting of the Company included in this Annual Report on Form 20-F for the year ended December 31, 2020.

KOST FORER GABBAY & KASIERER

A member of Ernst & Young Global

Tel Aviv, Israel
February 24, 2021