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, 2021

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	Trading Symbol	Name of Each Exchange on which Registered
Ordinary Shares, par value NIS 1.00 each	KMDA	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, 2021, the Registrant had 44,799,794 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 strategy to focus on driving profitable growth from our current commercial activities as well as our distribution, manufacturing, and development expertise in the plasma-derived and biopharmaceutical markets;*

- *our current exception to generate fiscal year 2022 total revenues at a range of $125 million to $135 million which would represent a 20% to 30% growth compared to fiscal year 2021;*

- *our current anticipation of generating EBITDA, during 2022, at a rate of 12% to 15% of total revenues, representing more than 2.5x of the EBITDA for the year ended December 31, 2021;*

- *our commitment to growing our hyperimmune immunoglobulins (IgG) portfolio and our plasma collection capabilities, and believe these acquisitions are a significant strategic step in that direction;*

- *our expectation that based on current GLASSIA sales in the U.S. 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 that, subject to EMA and subsequently IMOH approvals, we will launch in Israel eleven biosimilar products between the years 2022 and 2028, and our estimate that the potential aggregate maximum revenues, achievable within several years of launch, generated by the distribution of all eleven biosimilar products will be more than $40 million annually;*

- *our continued focus on driving profitable growth through expanding our growth catalysts which include: investment in the commercialization and life cycle management of the newly acquired products portfolio– CYTOGAM®, HEPGAM B®, VARIZIG® and WINRHO® SDF, including growing the acquired portfolio's revenues in new geographic markets; continued market share growth for our anti-rabies immunoglobulin products, KEDRAB® in the U.S. market; expanding sales of GLASSIA and other Proprietary products in ex-U.S. markets, including registration and launch of the products in new territories; generating royalties from GLASSIA sales by Takeda; expanding our plasma collection capabilities in support of our growing demand for hyper-immune specialty plasma as well as sales of normal source plasma to the market; continued increase of our Distribution segment revenues specifically through launching the eleven biosimilar products in Israel; and leveraging our FDA-approved IgG platform technology, manufacturing, research and development expertise to advance development and commercialization of additional product candidates including our Inhaled AAT product ("AATD") candidate and identify potential partners for this product;*

- *in connection with the acquisition of a portfolio of four FDA approved plasma-derived hyperimmune commercial products – CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF – from Saol Therapeutics ("Saol"), a commercial specialty pharmaceutical company focused on addressing the medical needs of underserved or unserved patient populations, our expectation to recruit staff as needed, and will gradually assume all operation responsibility related to the acquired products from Saol, including distribution and sales, quality procedures, supply chain activities, regulatory and finance related issues;*

- *our intention to market and distribute CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF directly based on our existing sales and marketing personnel as well as new, to be hired, sales and marketing employees, mainly in the U.S, and our intention to leverage our existing strong international distribution network to grow the acquired portfolio's revenue in geographic markets in which these products are not currently sold;*

- *our expectation to receive FDA approval for manufacturing of CYTOGAM and initiate commercial manufacturing of the product in our manufacturing facility in Beit Kama, Israel by early 2023;*

- *our expectation to continue manufacturing HEPAGAM B, VARIZIG and WINRHO SDF at Emergent BioSolutions Inc. ("Emergent") in the foreseeable future, while initiating in parallel a technology transfer project for transitioning the manufacturing of these products to our manufacturing facility in Beit Kama, Israel, subject to executing an amendment to the manufacturing services agreement with Emergent covering the technology transfer related services and scope, and our anticipation that once initiated, such project may be completed within three to five years;*

- *our plans to significantly expand our hyperimmune plasma collection capacity by investing in this plasma collection center in Beaumont, Texas, and leveraging our FDA license to establish a network of new plasma collection centers in the United States, with the intention to collect normal source as well as hyperimmune specialty plasma required for manufacturing of our other Proprietary products including KAMRAB/KEDRAB as well as for some of the products included in our recently acquired products portfolio;*

- *our intention to expand our Proprietary plasma-derived products business, including that of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF, by maximizing the market potential of our existing Proprietary products portfolio;*

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

- *our intention to enhance our current manufacturing capabilities;*

- *our plan to continue to develop our pipeline, primarily focusing on the pivotal Phase 3 InnovAATe clinical trial of Inhaled AAT for the treatment ofAATD 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 projection that the number of Solid Organ Transplants ("SOT") procedures performed will continue to grow at a rate of 6.5% over the next five years;*

- *our belief, based on CMV hyperimmune clinical evidence, that to improve transplant outcomes in combination with antiviral therapy, the administration of CYTOGAM together with the available antivirals can serve as a preferred option for preventing CMV disease;*

- *our belief that there is an under-usage of CYTOGAM to prevent CMV disease in SOT due to low awareness of its benefits when used with antiviral therapy for high-risk patients, our intention to engage in increased activities in order to promote the awareness for such benefits, and our belief that increased awareness can support higher usage rates;*

- *our intention to seek registration of CYTOGAM in various other territories as well as explore label expansion of CYTOGAM to be used in other indication;*

- *our belief that as the only Rho (D) product positioned in the U.S. for ITP and given its advantage over IVIG in treatment of acute ITP, increasing awareness amongst treating physicians can support higher usage rates;*

- *our belief that given the continued increase in liver transplants in the U.S. as well as several ex-U.S. countries, and with direct marketing efforts HEPAGAM usage may grow;*

- *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, including CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF, 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 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 ability to identify growth opportunities for existing products and our ability to identify and develop new product candidates;*

- *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 expectation to expand enrolment in the pivotal Phase 3 InnovAATe clinical trial through the planned opening, during the first half of 2022, of up to six additional sites in Europe;*

- *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, 2022.*

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, 2021, 2020 and 2019 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 3.11, the exchange rate published by the Bank of Israel as of December 31, 2021.

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. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business, liquidity, financial condition, and results of operations could be adversely affected, and even materially so, if any of the risks described below occur. As a result, the trading price of our securities could decline, and investors could lose all or part of their investment. This Annual Report including the consolidated financial statements contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially and adversely from those anticipated, as a result of certain factors, including the risks facing the Company as described below and elsewhere in the Annual Report. You should carefully consider the risks and uncertainties included herewith. 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. Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

- *Our ability to realize the anticipated benefits from the acquisition of four FDA approved plasma-derived hyperimmune commercial products CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF - is critical to our future growth, profitability and financial stability.*
- *Revenues and profitability expected to be generated from CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF as well as expected GLASSIA royalties for Takeda may not be enough to fully offset the decrease in revenues and profitability resulting from the cessation of GLASSIA sales to Takeda.*
- *A significant portion of our net revenue has been and will continue to be driven from sales of our proprietary products, and in our largest geographic region, the United States. Any adverse market event with respect to some of our proprietary products or the United States would have a material adverse effect on our business.*
- *We may have excess manufacturing plant capacity in our manufacturing facility, which may result in significant reduction in operating profits.*
- *We recently established our U.S. plasma collection operations and we intend to invest in expanding this activity in order to become independent in terms of plasma supply needs as well as to generate sales from commercialization of collected normal source plasma, and our ability to successfully expand this operation is critical to our support our future growth and profitability.*
- *We have several product development candidates, including our Inhaled AAT for AATD, as well as several other 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.*
- *We rely in large part on third parties for the sale, distribution and delivery of our products, and any disruption to our relationships with these third-party distributors would have an adverse effect on our future results of operations and profitability.*
- *In our Proprietary Product segment, we rely on Contract Manufacturing Organizations to manufacture some of our products and any disruption to our relationship with such manufacturers would have an adverse effect on the availability of products, our future results of operations and profitability.*

- *We could 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 Distribution segment is dependent on a small number of customers and suppliers, and any disruption to our relationship with them, or their inability to acquire or supply the products we sell, respectively would have a material adverse effect on our business, financial condition and 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.*

- *If our manufacturing facility in Beit Kama, Israel was 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 our products, all of our manufacturing capacity could be shut down for an extended period.*

- *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.*

- *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.*

- *We have incurred significant losses since our inception and while we were profitable in the five years ended December 31, 2021, we may incur losses in the future and thus may never achieve sustained profitability.*

- *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. Despite our indebtedness, we may still incur significantly more debt.*

- *Our share price may be volatile.*

- *Conditions in Israel could adversely affect our business.*

Risks Related to Our Business

We recently completed a strategic acquisition of four FDA approved plasma-derived hyperimmune commercial products – CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF; our ability to realize the anticipated benefits from this acquisition is critical to our future growth, profitability and financial stability.

In November 2021, we acquired a portfolio of four FDA approved plasma-derived hyperimmune commercial products, CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF, from Saol. The combined annual global revenue of the acquired portfolio in 2021 was approximately $41.9 million, of which our revenue was approximately $5.4 million and represents the sales generated from the date of consummation of the transaction through December 31, 2021. Approximately 75% and 21% of the annual sales of the acquired portfolio generated in the U.S. and Canada, respectively.

In connection with the acquisition, we entered into a transition services agreement with Saol, for the provision of certain required services (including, managing sales and distribution, payment collection, logistics management, price reporting, medical inquiries, QC complaints and pharmacovigilance), to secure the smooth transfer of the acquired assets and related commitments. We plan to gradually assume all operation responsibility related to the acquired products, including distribution and sales, quality procedures, supply chain activities, regulatory and finance related issues.

These products are currently distributed in the U.S. and Canadian markets, in which we intend to market and distribute these products directly based on our existing sales and marketing personnel as well as new, to be hired, sales and marketing employees, mainly in the U.S. In addition, the acquisition added eight new international markets, primarily in the Middle East and North Africa region in which we currently have little to know prior operational experience. We also intended to leverage our existing strong international distribution network to grow the acquired portfolio's revenue in geographic markets in which these products are not currently sold.

HEPGAM B, VARIZIG and WINRHO SDF are currently manufactured by Emergent pursuant to a contract manufacturing agreement assumed by us as part of the acquisition. We are currently in advanced stages of a technology transfer of CYTOGAM manufacturing to our plant in Beit Kama, Israel, and we plan to initiate a similar process to gradually transition the manufacturing of HEPGAM B, VARIZIG and WINRHO SDF to our plant as well, subject to the execution of an amendment to the contract manufacturing agreement.

Our ability to successfully transition and assume all required responsibilities with respect to these products, establish a U.S. based commercial and distribution infrastructure, maintain and expand ex-U.S. commercialization of these products, complete the technology transfer and obtain required approval for manufacturing of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF, is critical for our future growth, profitability and financial stability. Given our limited prior experience in some of the required activities and responsibilities, including operation of direct sales in the U.S. market, knowledge and experience in the eight new international markets, as well as other operational, technical, regulatory and financial challenges, we may not be able to realize the anticipated benefits of the acquisition, which may materially adversely affect the growth and operating results of our business as well as our financial condition.

Revenues and profitability expected to be generated from CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF as well as expected GLASSIA royalties for Takeda may not be enough to fully offset the decrease in revenues and profitability resulting from the cessation of GLASSIA sales to Takeda

We market GLASSIA in the United States through a strategic partnership with Takeda. Our 2021 revenues from the sale of GLASSIA to Takeda totaled $26.2 million, as compared to $64.9 million and $68.1 million during 2020 and 2019, respectively. During 2021 Takeda completed the technology transfer of GLASSIA manufacturing and initiated its own production of GLASSIA for the U.S. market, resulting in the cessation of GLASSIA sales to Takeda during 2021 and the significant reduction in sales. Commencing in 2022, Takeda will pay royalties, on sales of GLASSIA manufactured by Takeda, 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 U.S. and forecasted future growth, we expect to receive royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040.

In November 2021, we acquired a portfolio of four FDA approved plasma-derived hyperimmune commercial products – CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF – from Saol. The combined annual global revenue of the acquired portfolio in 2021 was approximately $41.9 million, of which our revenue was approximately $5.4 million and represents the sales generated from the date of consummation of the transaction through December 31, 2021.

The cessation of GLASSIA manufacturing by us, the transfer of manufacturing to Takeda and the transition to the royalty phase will result in a significant reduction of our revenue and profitability, and there can be no assurance that the revenues and profitability expected to be generated from the sales of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF will be enough to offset such expected reduction.

A significant portion of our net revenue has been and will continue to be driven from sales of our proprietary products, and in our largest geographic region, the United States. Any adverse market event with respect to some of our proprietary products or the United States would have a material adverse effect on our business

A significant portion of our revenues has been, and will continue to be, derived from sales of our proprietary products, including those of GLASSIA and KEDRAB as well as the recently acquired portfolio of four FDA approved plasma-derived hyperimmune commercial products, CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF. Revenue from our Proprietary products comprised approximately 73%, 76% and 77% of our total revenues for the years ended December 31, 2021, 2020 and 2019, respectively.

If some of our proprietary products 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 and North America, which comprised approximately 48%, 63% and 66% of our total revenues for the years ended December 31, 2021, 2020 and 2019, respectively. In addition, approximately 75% of the recently acquired CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF are expected to be generated in the United States. 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.

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 in 2021, we have been and may continue to be affected by reduced efficiency of our manufacturing facility, which resulted and may continue to result in 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 proprietary products, including KEDRAB and GLASSIA, which are currently manufactured in our facility, to facilitate, subject to completion of the technology transfer activities and regulatory approval, CYTOGAM commercial manufacturing, as well as for future manufacturing of HEPGAM B, VARIZIG and WINRHO SDF, subject to a technology transfer and regulatory approvals. While we have the knowhow and expertise to support the technology transfer of products to our facility, we may not be able to complete such transfer of any of the newly acquired portfolio products in the expected timeline, or at all. While we are capable of increasing the manufacturing capacity at our facility, 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. See also *"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 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 additional 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."*

We recently established our U.S. plasma collection operations and intend to invest in expanding this activity in order to become independent in terms of plasma supply needs as well as to generate sales from commercialization of collected normal source plasma, and our ability to successfully expand this operation is critical to support our future growth and profitability.

In March 2021, we acquired 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"). The acquisition of B&PR's plasma collection center represented our entry into the U.S. plasma collection market. We are in the process of significantly expanding our hyperimmune plasma collection capacity by investing in the acquired plasma collection center in Beaumont, Texas, and initiated a project to leverage our FDA plasma collection license to establish a network of new plasma collection centers in the United States, commencing in 2022, with the intention to collect normal source plasma for distribution, as well as hyperimmune specialty plasma required for manufacturing of our Proprietary products, including KAMRAB/KEDRAB, as well as for some of the products included in our recently acquired products portfolio. Our ability to support future growth and profitability is related, in part to the successful expansion of this operation.

Given our limited prior experience in managing plasma collection operations, the operational, technical, and regulatory challenges in maintaining plasma collection operations, as well as the financial investment required to expand our collection capabilities and open new collection centers, we may not be able to realize the anticipated benefits of such activities. We may not be able to adequately collect all sufficient quantities of plasma through our plasma collection operations to support our plasma sourcing needs, which will result in continued dependency on third party suppliers; and even if we are successful in collection sufficient quantities, 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 procuring plasma from third parties. In addition, there could be no assurance that we will be able to collect adequate quantities of normal source plasma as well as secure supply agreements with customer at adequate prices.

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."*

We have several product development candidates, including our Inhaled AAT for AATD as well as several other 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.

We are engaged in research and development activities with respect to several pharmaceutical products candidates, including Inhaled AAT for AATD, which is our lead product development candidate.

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. While a recent Data and Safety Monitoring Board (DSMB) review that concluded that the data generated to date support the continuation of the trial without the need for modifications, 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. Given the increased vaccination rate of the population as well as approvals of monoclonal antibodies for COVID-19, we are currently evaluating the market potential of this product and the continuation of its development program. There can be no assurance that we will be able to successfully complete this development program or that it would serve 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 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 or sell assets, businesses, products or technologies or engage in in-license or out-license transactions of products or technologies or form collaborations 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 acquire or sell assets, businesses, or products; or otherwise engage in in-licensing our out-licensing transactions with respect to products or technologies; or enter into other strategic alliances or collaborations. We may not identify suitable 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 or dispositions. Integration of an acquired company or assets into our existing business or a transition of an asset to an acquirer or partner 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.

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 may 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 reductions in inbound and outbound international delivery routes, which caused, and may continue to cause, delays in receipt of raw material and shipment of finished products, as well as 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, 2021 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, in the U.S. and Rest of World ("ROW") markets 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 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 12%, 14% and 13% of our total revenues in the years ended December 31, 2021, 2020 and 2019, respectively. We are dependent on Kedrion for its marketing and sales of KEDRAB in the United States.

We also primarily depend upon KedPlasma LLC ("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*."

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. 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. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

Our ability to assume full responsibility for the commercialization and sales of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF in the U.S. market is critical in order to support future growth, future results of operations and profitability.

Pursuant to a transition services agreement we entered into with Saol, we currently rely on Saol's commercial infrastructure and prior experience to sell and distribute CYTOGAM, HEPGAM B, VARIZIG and WINRHO SD world-wide. Sales of these products in the U.S. market represent approximately 75% of their world-wide sales. We initiated activities to establish a U.S. based commercial and sales team to gradually take over the U.S. commercial responsibility for these products. Such activities include hiring employees with relevant U.S. commercial experience, engaging wholesalers, customers and a U.S. third-party logistics (3PL) provider, and understanding market landscape and trends for these products through market research and discussions with physicians and key opinion leaders. These activities are crucial for our ability to assume all commercial operations from Saol and are necessary in order to successfully maintain sales levels and identify growth opportunities.

Given our limited prior experience in directly managing U.S. commercial operations and the operational, technical and regulatory challenges in maintaining such activity, we may not be able to realize the anticipated benefits of such activities. We may not be able to adequately and timely assume all responsibility or secure the required engagements or maintain or expand market demand and continued product sales, which may result in significant reduction in sales, increased operating costs and reduced 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.

Commencing in 2022, we are entitled to royalty payments form Takeda on GLASSIA sales 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.

We rely in large part on third parties for the sale, distribution and delivery of our products, and any disruption to our relationships with these third party distributors would have an adverse effect on our future results of operations and profitability.

We engage third party distributors to distribute and sell our Proprietary Products, including those of the recently acquired products CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF. Sales through distributors in ex-U.S. markets (other than the Israeli market) accounted for approximately 17%, 10% and 8% of our total revenues in the years ended December 31, 2021, 2020 and 2019, respectively and we expect such sales to increase in 2022 and beyond. We are dependent on these third parties for successful marketing, distribution and sales of our products in these markets. If such third parties were to breach, terminate or otherwise fail to perform under our agreements with them, our ability to effectively distribute our products would be impaired and our business could be adversely affected. Moreover, circumstances outside of our control such as a general economic decline, market saturation or increased competition may influence the successful renegotiation of our contracts or the securing of to us favorable terms.

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 biopharmaceutical companies, including several large competitors in the plasma industry 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 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.

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 antivirals, gene therapies, small molecules, correctors, monoclonal or recombinant products, may also be developed for indications for which our products are now used.

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.

KAMRAB/KEDRAB, our anti-rabies IgG products and KAMRHO (D) face competition in the U.S. and ex-U.S. markets.

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 currently two additional main suppliers of competitive products in this market: Grifols and CSL There are also local producers in other countries that make similar products mostly intended for local markets.

The newly acquired CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF face competition from several competing plasma derived products and non-plasma derived pharmaceuticals, mainly anti-viral.

CYTOGAM. To our knowledge, CYTOGAM is the sole FDA-approved CMV IgG product. Based on available public information, the FDA approved antiviral drugs for the prevention of CMV infection and disease, Letermovir (Prevymis), developed by Merck & Co., and for treatment of refractory infection or disease Maribavir (Livtencity), developed by Takeda, which may result in the loss of market share for CYTOGAM. Currently, treatment guidelines state that combination therapy with standard antiviral can be considered for certain solid organ transplant recipients. The most commonly used antivirals are Ganciclovir (Cytovene-IV Roche), Valgnciclovir (Valcyte Roche) and Valacyclovir (Valtrex GSK). Patients treated with such antivirals for a long time can develop resistance and will require a second line treatment such as Foscarnet (Foscavir Pfizer). In ROW markets, several plasma derived competing products are available, such as MEGALOTECT CP (Biotest).

WINRHO SDF. In the United States, WINRHO SDF competes with corticosteroids (oral prednisone or high-dose dexamethasone) or IVIG (Grifols, CSL and Takeda are the main manufacturers in the U.S.) as first line treatment of acute ITP. IVIG has similar efficacy to WINRHO SDF, and ITP is a labeled indication. Rhophylac (CSL Behring) is also approved for ITP treatment, but we believe it is mostly used for Hemolytic Disease of the Newborn (HDN), due to its comparatively small vial size. For HDN indication, the market is usually led by tenders, where key indicators are registration status and price, and the main multiple competitors in Canada and ROW countries are RhoGAM (Kedrion), Hyper RHO (Grifols) and Rhophylac (CSL Behring) and our KAMRHO (D).

HEPAGAM B. HEPAGAM B is the only approved HBIG with an on-label indication for Liver Transplants in the United States. To our understanding, HEPAGAM B holds the majority market share for the indication, while another HBIG (Nabi-B developed by ADMA) is being used off-label by some medical centers for the indication. In recent years, duration of treatment has been reduced by physicians. New generation antivirals are considered effective for preventing HBV reactivation post-transplant, hence limiting HBIG use. Post-exposure prophylaxis (PEP) indication in the United States is covered almost totally by Nabi-B (ADMA) and HyperHEP (Grifols). In Canada, main competition in national tenders is HypeHEP. In ROW countries such as Turkey, Saudi-Arabia and Israel, HEPATECT CP (Biotest AG) represents the primary competition.

VARIZIG. In the United States, incidence of Varicella Zoster Virus ("VZV") infection has decreased dramatically since the introduction of the varicella vaccine in 1995. Two vaccines containing varicella virus are licensed for use in the United States. Varivax is the single-antigen varicella vaccine. ProQuad is a combination measles, mumps, rubella, and varicella (MMRV) vaccine. Although the use of the vaccine has reduced the frequency of chickenpox, the virus has not been eradicated. Moreover, incidence of Herpes Zoster, also caused by VZV, is increasing among adults in the United States. Suboptimal vaccination rates contribute to outbreaks and increased risk of VZV exposure. Immunocompromised population and other patient groups are at high risk for severe varicella and complications, after being exposed to VZV. To our knowledge, to date, in the United States market VariZIG is a single FDA-approved product and recommended by the Centers for Disease Control (CDC) for post-exposure prophylaxis of varicella for persons at high risk for severe disease who lack evidence of immunity to varicella. In ROW markets, several plasma derived competitor products are available, such as VARITECT (Biotest) and others.

Our market share of the AAT product could be negatively impacted by new competitors or adoption of new methods of administration.

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. In the U.S. Grifols sell Prolastin Liquid since 2018, which is a ready-to-infuse solution of AAT. 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, Zemaira, is mainly sold in the United States. In 2015, CSL's intravenous AAT product, Respreeza, 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.

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.

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.

Our Anti-SARS-CoV-2 IgG product faces, or may face, significant competition from competitors developing COVID-19 related therapies.

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. The Alliance produced a plasma derived hyperimmune therapy similar to our investigational product. The Alliance product was tested in Phase 3 clinical trial sponsored by the National Institute of Allergy and Infectious Diseases ("NIAID"), part of the National Institutes of Health (the "NIH"), and on April 2, 2021, Takeda and CSL Behring announced that the Phase III clinical trial did not meet its endpoints. With that, the collaboration of the companies in the Alliance has ended.

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 cold-chain handling, all of which could adversely affect our operating results.

Plasma and its derivatives 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 continued adherence by us and contract manufacturers to current Good Manufacturing Practice regulations.

The manufacturing processes for our products are governed by detailed written procedures and regulations that are set forth in 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 or contract manufacturers 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.

The adherence by us and our contract manufacturers to cGMP regulations and the effectiveness of applicable quality control systems are periodically assessed through inspections of the manufacturing facility, including 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 or our contract manufacturers to take action to correct those deficiencies to the satisfaction of the applicable regulatory authorities. If serious deficiencies are noted or if we or our contract manufacturers 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 or our contract manufacturers 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, 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.

Continued availability of CYTOGAM is dependent on our ability to complete the technology transfer of its manufacturing to our manufacturing facility in Beit Kama, Israel as well as our ability to maintain continues plasma supply.

As part of the acquisition of the four FDA approved plasma-derived hyperimmune commercial products from Saol, we acquired certain excess inventories of CYTOGAM which is sufficient to meet market demand through mid-2023. During 2019, pursuant to an engagement with Saol, we initiated technology transfer activities for transitioning CYTOGAM manufacturing to our manufacturing facility in Beit Kama, Israel. The process is already well underway, and we expect to receive FDA approval for manufacturing of CYTOGAM and initiate commercial manufacturing of the product by early 2023. Failure to timely complete the technology transfer and obtain the required regulatory approvals may affect product availability, result in a decrease in sales and a deterioration in our market share, and could have an adverse effect upon our sales, margins and profitability.

As part of the technology transfer process initiated, we engaged a third-party contract manufacturer that performs certain manufacturing activities required for the manufacturing of CYTOGAM. In addition, we assumed a plasma supply agreement with CSL for continued supply of required plasma for the manufacturing of the product. If we fail to maintain our relationship with these entities, we could face increased costs in finding replacement vendors Delays in establishing a relationship with new vendors could lead to a decrease in the product's sales and a deterioration in our market share when compared with one or more of our competitors. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

In our Proprietary Product segment, we rely on Contract Manufacturing Organizations to manufacture some of our products and any disruption to our relationship with such manufacturers would have an adverse effect on the availability of products, our future results of operations and profitability.

HEPAGAM B, VARIZIG and WINRHO SDF are manufactured by Emergent under a contract manufacturing agreement which was assigned to us from Saol following the consummation of the acquisition. We are dependent on Emergent to secure supply of adequate quantities of plasma needed to timely manufacture these products and we rely on their manufacturing, quality and regulatory systems to ensure the manufacturing process comply with cGMP and any other regulatory requirement and that each product manufactured meets its specification and is appropriately released for human consumption.

If we fail to maintain our relationship with Emergent, we could face increased costs in finding a replacement manufacturer for these products and we might be required to identify replacement supplier of the plasma which is used for the production of these products. Delays in establishing a relationship with a new manufacturer could lead to a decrease in these products sales and a deterioration in our market share when compared with one or more of our competitors. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

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.

The manufacturing of newly marketed or investigational plasma-derived products in our plant, including the four hyper-immune globulin products recently acquired from Saol, 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 manufactured 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 meet commercial demand, utilize the excess capacity of our manufacturing plant, incur additional costs and may suffer reduced profitability or operating losses.

Disruption of the operations of our current or any future plasma collection center due to regulatory impediments or otherwise would cause us to become supply constrained and our financial performance would suffer.

In March 2021, we completed the acquisition of the FDA licensed plasma collection center and certain related assets from 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. We plan to significantly expand our hyperimmune plasma collection capacity by investing in this plasma collection center in Beaumont, Texas, and leveraging our FDA license to open additional centers in the United States.

In order for plasma to be used in the manufacturing of our products, the individual centers at which the plasma is collected must be licensed and approved by the regulatory authorities, such as the FDA and the EMA, of those countries in which we sell our products. When a new plasma collection center is opened, it must be inspected on an ongoing basis after its approval by the FDA and the EMA for compliance with cGMP and other regulatory requirements, and these regulatory requirements are subject to change. An unsatisfactory inspection could prevent a new center from being approved for operation or risk the suspension or revocation of an existing approval. In order for a plasma collection center to maintain its governmental approval to operate, its operations must continue to conform to cGMP and other regulatory requirements or recommendations which may be applicable from time to time (e.g., in January 2022, the FDA issued guidance providing recommendations to blood establishments on collection of convalescent plasma during the public health emergency).

In the event that we determine that our 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 would be recorded as a charge to cost of goods. 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. Consequently, we could experience significant inventory impairment provisions and write-offs.

We plan to continue to obtain our supplies of plasma for use in our manufacturing processes through collections at our plasma collection centers and through the establishment of new plasma collection centers. We also plan to expand collection programs to include hyperimmune specialty plasma required for manufacturing of our Proprietary products including KAMRAB/KEDRAB as well as for some of the products included in our recently acquired products portfolio. This strategy is dependent upon our ability to successfully establish new centers, to obtain FDA and other necessary approvals for any centers not yet approved by the FDA, to maintain a cGMP compliant environment in all centers and to attract donors to our centers.

Our ability to increase and improve the efficiency of production at our current or any future plasma collection center may be affected by: (i) changes in the economic environment and population in selected regions where we operate plasma collection centers; (ii) the entry of competitive centers into regions where we operate; (iii) our misjudging the demographic potential of individual regions where we expect to increase production and attract new donors; (iv) unexpected facility related challenges; or (v) unexpected management challenges at select plasma collection centers.

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 and those of our contract manufacturers 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, while we recently entered the U.S. plasma collection market with our recent acquisition of a plasma collection center in the United States, we continue to rely on, Kedrion, CSL, Emergent, Takeda and additional plasma suppliers, for plasma collection required for the manufacturing of KEDRAB, CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF, GLASSIA 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 for us, these plasma suppliers are required to comply with certain regulatory requirements. Any failure by these 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 each of KEDRAB, CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF GLASSIA 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.

Changes in our production processes for our products may require supplemental submissions or prior approval by 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.

Pursuant to the amendment to the GLASSIA license agreement with Takeda, entered into in March 2021, we agreed to transfer the U.S. Biologics License Application ("BLA") to Takeda. Following the effectiveness of such transfer, we will rely on Takeda to share with us any relevant information with respect to changes in the manufacturing of the product or its usage which may be applicable in order to update the products registration file in certain ROW markets in which it is currently registered and/or distributed, or may be registered and/or distributed in the future.

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, some of which are also responsible for the plasma fractionation process, pursuant to multiple purchase agreements. We have entered into (and with respect to the recently acquired four FDA approved products, we assumed) a number of plasma supply agreements with various third parties in the United States and Europe. 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. 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.

The 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 decreases, 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, if these suppliers fail to meet our vendors qualification processes, 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 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 rise 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 rise, 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 and for KEDRAB. 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 may 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 that is conditioned 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 Biotest A.G., Chiesi Farmaceutici S.p.A and Bio Products Laboratories Ltd. ("BPL"), which are sold in our Distribution segment, together represented approximately 25%, 22% and 19% of our total revenues for the years ended December 31, 2021, 2020 and 2019, 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 42%, 41% and 47% of our Distribution Segment revenues in the years ended December 31, 2021, 2020 and 2019, 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 face significant competition in our Distribution segment from companies with greater financial resources.

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.

In 2020 and 2021, we 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 to be obtained by the manufacturer of the biosimilar product from the FDA or the EMA. 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, 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 initiated the development of our investigational Anti-SARS-CoV-2 IgG product in the wake of the COVID-19 pandemic, due to the lengthy and costly development and required regulatory process as well as the dependency on continued collection and supply of plasma from COVID-19 convalescent patients and competitive landscape, 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 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 meet recruitment targets in time. While we plan to open a few new study sites despite the continuation of the pandemic, there can be no assurance that we will be able to open any additional sites or 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 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 the following:

- 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 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 several 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 and 2021, 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, 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.

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 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.

Lastly, we rely on PARI to ensure that the eFlow device is not violating or infringing on any third party intellectual property or patents. PARI's inability to ensure its freedom to operate may have a significant effect on our ability to continue the development of our Inhaled AAT product candidate as well as potentially commercializing it.

Risks Related to Our Operations and Industry

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 manufacturers 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 separately impose 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.

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 U.S. Securities and Exchange Commission (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.

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. A significant part of our revenues in our Proprietary Products segment were derived, and are expected to continue to be 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.

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.

Failure to maintain the security of protected health 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 and other personal 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 litigation costs and damages, 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. Furthermore, U.S. federal and state regulators continue to adopt new, or modify existing laws and regulations addressing data privacy and the collection, processing, storage, transfer and use of data, including the U.S. Health Insurance Portability and Accountability Act of 1996, as amended, and implementing regulations ("HIPAA"). These privacy, security and data protection laws and regulations could impose increased business operational costs, require changes to our business, require notification to customers or workers of a security breach, or restrict our use or storage of personal information. Our efforts to implement programs and controls that comply with applicable data protection requirements are likely to impose additional costs on us, and we cannot predict whether the interpretations of the requirements, or changes in our practices in response to new requirements or interpretations of the requirements, could have a material adverse effect on our business.

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 and health 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. Ultimately, CMS published a final rule on December 27, 2021 rescinding the Most-Favored-Nation model interim final rule and removing the associated regulatory text effective as of February 28, 2022. Similar federal, state and foreign government efforts in the future 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. On November 27, 2020, the U.S. Trade Representative submitted a proposal to withdraw these drugs and medical devices identified by the FDA from U.S. commitments under the World Trade Organization Government Procurement Agreement (WTO GPA). On April 20, 2021, President Joe Biden ultimately withdrew this proposal. The withdrawal of this proposal allows the U.S. government to continue purchasing foreign-made drugs and medical devices as permitted under the Trade Agreements Act, and effectively counter's President Trump's August 2020 Executive Order directing the government to purchase domestically-produced essential drugs and medical devices. However, on January 25, 2021, President Joe Biden issued the Executive Order on Ensuring the Future Is made in All of America by All of America's Workers (Executive Order 14005) to maximize the use of goods, products, materials produced in, and services offered in the United States, which may affect FDA-related products. The full effect of the Executive Order and the withdrawal of the WTO proposal on our commercial operations and results of operations cannot currently be estimated.

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. On November 16, 2020, the U.S. Health and Human Services (HHS) Office of Inspector General (OIG) issued a Special Fraud Alert discussing the fraud and abuse risks associated with payments to physicians related to speaker programs sponsored by pharmaceutical and medical device companies. OIG expressed skepticism regarding the educational value of these industry-sponsored speaker programs and warned of the inherent fraud and abuse risks of these programs.

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 HHS 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 are in the process of adopting U.S. healthcare compliance and ethics programs that generally incorporate the HHS OIG's recommendations; however, there can be no assurance that following the adoption of such programs 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.

If we fail to comply with our obligations under U.S. governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions and fines.

The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid rebate program will increase our costs and the complexity of compliance and will be time-consuming. Changes to the definition of "average manufacturer price" (AMP), and the Medicaid rebate amount under the ACA and CMS and the issuance of final regulations implementing those changes has affected and could further affect our 340B "ceiling price" calculations. When we participate in the Medicaid rebate program, we are required to report "average sales price" (ASP), information to CMS for certain categories of drugs that are paid for under Part B of the Medicare program. Future statutory or regulatory changes or CMS binding guidance could affect the ASP calculations for our products and the resulting Medicare payment rate and could negatively impact our results of operations.

Pricing and rebate calculations vary among products and programs, involve complex calculations and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current AMP and "best price" for the quarter. If we become aware that our reporting for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. Such restatements and recalculations would increase our costs for complying with the laws and regulations governing the Medicaid rebate program. Price recalculations also may affect the "ceiling price" at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B/Public Health Service (PHS) drug pricing program.

In addition, if we are found to have made a misrepresentation in the reporting of ASP, we are subject to civil monetary penalties for each such price misrepresentation and for each day in which such price misrepresentation was applied. If we are found to have knowingly submitted false AMP or "best price" information to the government, we may be liable for civil monetary penalties per item of false information. Any refusal of a request for information or knowing provision of false information in connection with an AMP survey verification would also subject us to civil monetary penalties. In addition, our failure to submit monthly/quarterly AMP or "best price" information on a timely basis could result in a civil monetary penalty per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, under which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure that our submissions will not be found by CMS to be incomplete or incorrect.

In order for our products to be reimbursed by the primary federal governmental programs, we must report certain pricing data to the USG. Compliance with reporting and other requirements of these federal programs is a pre-condition to: (i) the availability of federal funds to pay for our products under Medicaid and Medicare Part B; and (ii) procurement of our products by the Department of Veterans Affairs (DVA), and by covered entities under the 340B/PHS program. The pricing data reported are used as the basis for establishing Federal Supply Schedule (FSS), and 340B/PHS program contract pricing and payment and rebate rates under the Medicare Part B and Medicaid programs, respectively. Pharmaceutical companies have been prosecuted under federal and state false claims laws for submitting inaccurate and/or incomplete pricing information to the government that resulted in increased payments made by these programs. Although we maintain and follow strict procedures to ensure the maximum possible integrity for our federal pricing calculations, the process for making the required calculations is complex, involves some subjective judgments and the risk of errors always exists, which creates the potential for exposure under the false claims laws. If we become subject to investigations or other inquiries concerning our compliance with price reporting laws and regulations, and our methodologies for calculating federal prices are found to include flaws or to have been incorrectly applied, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations.

To be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we also must participate in the DVA FSS pricing program. To participate, we are required to enter into an FSS contract with the DVA, under which we must make our innovator "covered drugs" available to the "Big Four" federal agencies-the DVA, the DoD, the Public Health Service (including the Indian Health Service), and the Coast Guard-at pricing that is capped under a statutory federal ceiling price (FCP) formula set forth in Section 603 of the Veterans Health Care Act of 1992 (VHCA). The FCP is based on a weighted average wholesale price known as the Non-Federal Average Manufacturer Price (Non-FAMP), which manufacturers are required to report on a quarterly and annual basis to the DVA. Under the VHCA, knowingly providing false information in connection with a Non-FAMP filing can subject us to significant penalties for each item of false information. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to disclose the error and refund the difference to the government. The failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, can be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 further collective bargaining agreement with the employees' committee and the Histadrut, which expired in December 2021, and we are currently in negotiations with the employees' committee on a new collective bargaining agreement. On March 3, 2022, during the course our negotiations with the Histadrut and the employees' committee on the extension of the collective bargaining agreement, the employee's committee elected to declare a labor dispute. 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 as a result of the transfer of GLASSIA manufacturing to Takeda that we implemented during 2021, 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.

Following the establishment of our U.S. commercial operations through our subsidiaries Kamada Inc. and Kamada Plasma LLC, we have entered into intercompany agreements for the transfer of products, which require us to meet transfer pricing requirements under both Israeli and U.S. tax legislation.

Following the establishment of our U.S. commercial operations through our subsidiaries Kamada Inc. and Kamada Plasma LLC, we have entered into intercompany agreements for the transfer of products. Our intercompany agreements for the sale of products or provision of services are required to be made on an arms-length basis and must comply with transfer pricing provisions of tax laws in Israel and the U.S. In order to determine the adequate transfer pricing arrangement, we are required to perform a transfer pricing study to compare the contemplated intercompany transaction with similar transactions entered into amongst non-related parties. There can be no assurance that the Israeli and/or tax authorities would accept such transfer pricing study when determining our, or any of our subsidiary's income, profitability and tax assessment. Failure to comply with transfer pricing rules may result in increased tax expenses, penalties and legal actions against us, our subsidiaries or our executive officer.

We may be exposed to tax reporting requirements and tax expense in multiple jurisdictions in which our products are being distributed.

We are incorporated under the laws of the State of Israel and some of our subsidiaries are organized under the laws of Delaware and Ireland and as a result, we are subject to local tax requirements and potential tax expenses in these territories. We store, distribute and sell our Proprietary products in multiple other countries in which we do not have any subsidiaries or physical presence; nevertheless, in some of these countries, pursuant to local legislation, we may be considered as "conducting business activities" which may expose us to certain reporting requirements and potential direct or indirect tax payments. Failure to comply with such local legislation may result in increased tax expenses, penalties and legal actions against us, our subsidiaries or our executive officers.

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 2041. 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.

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 the realm of our biosimilars distribution products, or 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 five years ended December 31, 2021, we may incur losses in the future and thus may never achieve sustained profitability.

As of December 31, 2021, our cash and cash equivalents and short-term investments were $18.6 million. Since inception, we have incurred significant operating losses including a loss of $2.2 million for the year ended December 31, 2021. While our net profit was $17.1 million and $22.3 million for the years ended December 31 2020 and 2019, respectively, as of December 31, 2021, we had an accumulated deficit of $46.2 million. While we believe that the recent acquisition of a portfolio of four FDA-approved plasma-derived hyperimmune commercial products from Saol represents an important growth driver and revenue source, there can be no assurance that such acquisition will be successful and we may not be able to continue to generate profitability in future years.

Our financial position and operations may be affected as a result of the indebtedness we incurred to partially fund the Saol acquisition.

On November 15, 2021, to partially fund the Saol acquisition, we obtained a $40 million debt facility from Bank Hapoalim B.M., comprised of a $20 million short-term revolving credit facility and a $20 million five-year loan. The indebtedness incurred may have significant adverse consequences on our business, including:

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions, or other general business purposes;

- require the use of a substantial portion of our cash to service our indebtedness rather than investing our cash to fund our strategic growth opportunities and plans, working capital and capital expenditures;
- expose us to the risk of increased interest rates as these borrowings are subject to the Secured Overnight Financing Rate (SOFR), (i) in the case of the long-term loan, SOFR + 2.18%; and (ii) in the case of the credit facility, SOFR + 1.75;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- increase our vulnerability to the impact of adverse economic, competitive and industry conditions;
- prevent us from pledging our assets as collateral, which could limit our ability to obtain additional debt financing;
- place us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity; and
- increase our cost of borrowing.

In addition, the terms of the loan and credit facility contain restrictive covenants that may limit our ability to engage in activities that may be in our long-term best interest. These restrictive covenants include, among others, limitations on restructuring, the sale of purchase of assets, material licenses, certain changes of control and the creation of floating charges over our property and assets. Under the terms of these facilities, we are also required to maintain certain financial covenants, including minimum equity capital, maximum working capital to debt ratio and minimum debt coverage ratio. Our failure to comply with those covenants could result in an event of default which, if not cured or waived, could result in the acceleration of substantially all of our debt.

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. Despite our indebtedness, we may still incur significantly more debt.

In order to obtain and maintain 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, 2021, we had cash and short-term investments of $18.6 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.

To service our indebtedness and other obligations, we will require a significant amount of cash and our ability to generate cash depends on many factors beyond our control.

The capability to pay and refinance our indebtedness and to fund working capital requirements and planned capital expenditures will depend on our ability to generate cash in the future. A significant reduction in our operating cash flows resulting from changes in economic conditions, increased competition or other events beyond our control could increase the need for additional or alternative sources of liquidity and could have a material adverse effect on our business, financial condition, results of operations, prospects and our ability to service our debt and other obligations. If we are unable to service our indebtedness through sufficient cash flows from operations, we will be forced to shift to alternative strategies, which may include the reducing of capital expenditures, the sale of assets, the restructuring or refinancing of our debt or the seeking of additional equity. We cannot assure that these alternative strategies, if any, could be implemented on satisfactory and commercially reasonable terms, that they would provide sufficient funds to make the required payments on our debt or to fund our other liquidity needs.

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 impact our financial information and 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 require significant resources to remediate, expose us to legal or regulatory proceedings, and 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 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 increased 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.

Our shareholders may experience significant dilution as a result of any additional financing using our equity securities or may experience a decrease in the share price due to sales of our equity securities.

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. Any additional capital raised through the sale of equity securities will likely dilute the ownership percentage of our shareholders.

Future sales of ordinary shares by affiliates could cause our share price to fall.

The FIMI Opportunity Funds own 9,452,708 of our outstanding ordinary shares (representing an ownership percentage of 21.1% of the outstanding shares and 20.45% 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 21.1%, 8.0% and 4.3% of our outstanding ordinary shares, respectively, as of March 15, 2022. 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 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 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 and the surrounding region may 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. 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.

Our commercial insurance does not cover losses that may occur as a result of events associated with war. Losses resulting from acts of terrorism may be partially covered under certain circumstance. Although the Israeli government currently covers certain value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business.

Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. 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.

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

As of December 31, 2021, we had 357 employees based in Israel. Certain of our Israeli 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 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. Under Israel's 2021-2022 Budget Law, published on November 15, 2021, in the event of a dividend distribution, earnings that were tax exempt under the historical Approved or Beneficial Enterprise regimes, referred to as "trapped earnings," must be distributed on a pro-rata basis from any dividend distribution, commencing August 15, 2021. In addition, under a temporary order in force for a one year period from its enactment on November 15, 2021, Israeli companies that have trapped earnings under the historical Approved and Beneficial Enterprise regimes, that are generally subject to a claw-back of the corporate tax rate that was not paid on such earnings upon their distribution, will be able to distribute such earnings with up to a 60% "discount" of the applicable corporate tax rate, but not less than a 6% corporate tax rate. The applicable corporate tax rate is determined based on a formula that considers the ratio of the "released" earnings out of the trapped earnings and the historical corporate tax rate the company was exempt from, and allows the maximum benefit if the entire amount of trapped earnings is to be released. 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, 2021, we had net operating loss carryforwards ("NOLs") for tax purposes of approximately $33 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 23 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.

General Risks

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.

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.

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.

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.

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.

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.

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, the U.S. House of Representatives has passed a bill that, if passed by the Senate, could have a significant impact on the U.S. tax system. While, at this point, we cannot predict the likelihood of U.S. tax reform in 2022 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.

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, or held to be unenforceable or circumvented.

Raising additional 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 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.

The Russian invasion of Ukraine may have a material adverse impact on us.

Commencing in 2021, Russian President Vladimir Putin ordered the Russian military to begin massing thousands of military personnel and equipment near its border with Ukraine and in Crimea, representing the largest mobilization since the illegal annexation of Crimea in 2014. President Putin has initiated troop movements into the eastern portion of Ukraine and continues to threaten an all-out invasion of Ukraine. On February 22, 2022, the United States and several European nations announced sanctions against Russia in response to Russia's actions. On February 24, 2022, President Putin commenced a full-scale invasion of Russia's pre-positioned forces into Ukraine, which could have a negative impact on supply chains and the economy and business activity globally. Furthermore, the conflict between the two nations and the varying involvement of the United States and other NATO countries could preclude prediction as to their ultimate adverse impact on global economic and market conditions, and, as a result, presents material uncertainty and risk with respect to our operations and the price of our shares.

Additionally, given the recent sanctions imposed on Russia we may not be able to continue and supply our products to our Russian distributor, and even if we will be able to continue the supply of product, there can be no assurance that our distributor may be able to pay us for such products given the recent actions taken by the Russian government to seize all international foreign currency payments. Our revenues, profitability and financial condition may be effected if we are unable to continue to sell our products to the Russian market and/or are not able to collect due proceeds from previous and/or future product sales.

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 vertically integrated global biopharmaceutical company, focused on specialty plasma-derived therapeutics, 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 as well as our manufacturing and development expertise in the plasma-derived and biopharmaceutical markets.

We operate in two segments: the Proprietary Products segment, which includes six FDA approved plasma-derived biopharmaceutical products (including the recently acquired portfolio of four FDA approved products) as well as additional plasma-derived products that we market internationally in more than 30 countries. We manufacture our proprietary products at our cGMP compliant FDA-approved production facility located in Beit Kama, Israel, using our proprietary platform technology and know-how for the extraction and purification of proteins and IgGs from human plasma, as well as at third party contract manufacturing facilities, 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.

As part of our strategy, we recently completed two acquisitions. In November 2021, we acquired a portfolio of four FDA approved plasma-derived hyperimmune commercial products – CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF – from Saol, a specialty pharmaceutical company focused on addressing the medical needs of underserved or unserved patient populations. The combined annual global revenue of the acquired portfolio in 2021 was approximately $41.9 million, of which our revenue was approximately $5.4 million and represents the sales generated from the date of consummation of the transaction through December 31, 2021. Approximately 75% and 21% of the 2021 annual sales of the acquired portfolio were generated in the U.S. and Canada, respectively. In March 2021, we completed the acquisition of the FDA licensed plasma collection center and certain related assets from 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. See below "— *Recent Acquisitions*." We are committed to growing our hyperimmune immunoglobulins (IgG) portfolio and our plasma collection capabilities, and believe these acquisitions are a significant strategic step in that direction.

In addition to the recently acquired products portfolio, our Proprietary products includes GLASSIA, an intravenous AAT product that is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to AATD, KAMRAB/KEDRAB, a plasma-derived hyper-immunoglobulin for prophylactic treatment against rabies infection administered to patients after exposure to a suspected rabid animal, KAMRHO (D) intramuscular ("IM") for prophylaxis of hemolytic disease of newborns, and KAMRHO (D) IV for treatment of immune thermobocytopunic purpura ("ITP"), as well as two types of anti-snake venom derived from equine plasma.

We market GLASSIA in the United States through a strategic partnership with Takeda. Our 2021 revenues from the sale of GLASSIA to Takeda totaled $26.2 million, as compared to $64.9 million and $68.1 million during 2020 and 2019, respectively. In addition, during 2021 we recognized revenues of $5.0 million on account of a sales milestone due from Takeda. During 2021, Takeda completed the technology transfer of GLASSIA manufacturing to its facility in Belgium and received the required FDA approval, and initiated its own production of GLASSIA for the U.S. market. In addition, during 2021, Takeda obtained a marketing authorization approval for GLASSIA from Health Canada. Commencing 2022, Takeda will pay us royalties, on sales, in the U.S. and Canadian markets of GLASSIA manufactured by Takeda, 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 and forecasted future growth, we expect 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 2021 was $7.6 million, as compared to $5.5 million and $5.5 million during 2020 and 2021, respectively.

We market KAMRAB in the United States under the trademark "KEDRAB" through a strategic distribution and supply agreement with Kedrion. Our 2021 revenues from sales of KEDRAB to Kedrion totaled $11.9 million as compared to $18.3 million and $16.4 million during 2020 and 2019, respectively. Sales of KEDRAB by Kedrion in the United States during the year 2021, 2020 and 2019 totaled $24.7 million, $23.7 million and $31.4 million, respectively. Based on information provided by Kedrion, these sales represent approximately 27%, 23% and 20% share of the relevant U.S. market in each of these years, respectively. The reduction of sales of KEDRAB to Kedrion during 2021 was a result of relatively higher level of inventory of product at Kedrion as of December 31, 2020, which was due to reduced KEDRAB sales by Kedrion during 2020 (as noted above) as a result of the effect of the COVID-19 pandemic.

Our 2021 revenues from the sales of the remaining Proprietary products, including KAMRAB (outside the U.S. market), KAMRHO (D) IM and IV, the anti-snake venom, as well as our development stage Anti-SARS-CoV-2 IgG product totaled $18.4 million, as compared to $11.2 million and $7.1 million during 2020 and 2019, respectively.

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 84%, 89% and 81% of our Distribution segment revenues for the years ended December 31, 2021, 2020 and 2019, respectively. Over the past several years we continued to extend our Distribution segment products portfolio to non-plasma derived products, including recently entering into an agreement with Alvotech and two additional companies for the distribution in Israel of eleven different biosimilar products which, subject to EMA and subsequently IMOH approvals, are expected to be launched in Israel between the years 2022 and 2028. We estimate the potential aggregate peak revenues, achievable within several years of launch, generated by the distribution of all eleven biosimilar products to be more than $40 million annually.

In addition to our commercial operation, we invest in research and development of new product candidates. Our leading investigational product is Inhaled AAT for AATD, for which we are continuing to progress the InnovAATe clinical trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial. We have additional product candidates in early development stage. For additional information regarding our research and development activities, see "*— Our Development Product Pipeline*."

We continue to focus on driving profitable growth through expanding our growth catalysts which include: investment in the commercialization and life cycle management of the newly acquired products portfolio, including growing the acquired portfolio's revenues in new geographic markets; continued market share growth for KEDRAB in the U.S. market; expanding sales of GLASSIA and our other Proprietary products in ex-U.S. markets, including registration and launch of the products in new territories; generating royalties from GLASSIA sales by Takeda; expanding our plasma collection capabilities in support of our growing demand for hyper-immune plasma as well as sales of normal source plasma to other plasma-derived manufacturers, ; continued increase of our Distribution segment revenues specifically through launching the eleven biosimilar products in Israel; and leveraging our FDA-approved IgG platform technology, manufacturing, research and development expertise to advance development and commercialization of additional product candidates, including our investigational Inhaled AAT product, and identify potential partners for this product.

We currently expect to generate fiscal year 2022 total revenues in the range of $125 million to $135 million which would represent a 20% to 30% growth compared to fiscal year 2021. We also anticipate generating EBITDA, during 2022, at a rate of 12% to 15% of total revenues, representing more than 2.5x of the EBITDA for the year ended December 31, 2021.

Recent Acquisitions

Acquisition of IgG portfolio

In November 2021, we acquired a portfolio of four FDA approved plasma-derived hyperimmune commercial products from Saol. For a description of the four products acquired from Saol, CYTOGAM, HEPAGAM B, VARIZIG and WINRHO SDF, see below "— Our Commercial Product Portfolio — *Proprietary Products Segment*." The acquisition of this portfolio furthers our core objective to become a fully integrated specialty plasma company with strong commercial capabilities in the U.S. market, as well as to expand to new markets, mainly in the Middle East/North Africa region, and to broaden our portfolio offering in existing markets. Our wholly owned U.S. subsidiary, Kamada Inc., will be responsible for the commercialization of the four products in the U.S. market, including direct sales to wholesalers and local distributers.

Under the terms of the agreement, we paid Saol a $95 million upfront payment, and agreed to pay up to an additional $50 million of contingent consideration subject to the achievement of sales thresholds for the period commencing on the acquisition date and ending on December 31, 2034. We may be entitled for up to $3.0 million credit deductible from the contingent consideration payments due for the years 2023 through 2027, subject to certain conditions as defined in the agreement between the parties. In addition, we acquired inventory valued at $14.4 million and agreed to pay the consideration to Saol in ten quarterly installments of $1.5 million each or the remaining balance at the final installment.

To partially fund the acquisition costs, we obtained a $40 million financing facility from the Israeli Bank Hapoalim B.M., comprised of a $20 million five-year loan and a $20 million short-term revolving credit facility. For information regarding the financing, see "Item 5. Operating and Financial Review and Prospects—Liquidity and Capital Resources—*Credit Facility and Loan Agreement with Bank Hapoalim B.M.*".

In connection with the acquisition, we entered into a transition services agreement with Saol, which defines the services and support to be provided by Saol to us for a defined period (including, managing sales and distribution, payment collection, logistics management, price reporting, regulatory affairs, medical inquiries, quality control complaints and pharmacovigilance), in order to secure the smooth transfer of the acquired assets and related commitments. The term of the transition services agreement for most services is estimated between three to six months following the closing of the acquisition. During the transition period, we will recruit staff as needed, and will gradually assume all operation responsibility related to the acquired products, including distribution and sales, quality procedures, supply chain activities, regulatory and finance related issues. The cost for services provided under the transition services agreement is based on the actual work to be performed by Saol, with monthly workload adjustments, and pass-through costs.

Pursuant to an earlier engagement with Saol, during 2019, we initiated technology transfer activities for transitioning CYTOGAM manufacturing to our manufacturing facility in Beit Kama, Israel. The process is already well underway, and we expect to receive FDA approval for manufacturing of CYTOGAM and initiate commercial manufacturing of the product in early 2023. As a result of the consummation of the IgG portfolio acquisition, which included the acquisition of all rights relating to CYTOGAM, the previous engagement with Saol with respect to this product expired.

In connection with the acquisition, we assumed a contract manufacturing agreement with Emergent for the manufacturing of HEPAGAM B, VARIZIG and WINRHO SDF. We expect to continue manufacturing these products with Emergent in the foreseeable future, while initiating in parallel a technology transfer project for transitioning the manufacturing of these products to our manufacturing facility in Beit Kama, Israel. The initiation of such technology transfer project is subject to executing an amendment to the manufacturing services agreement with Emergent covering the technology transfer related services and scope. We anticipate that once initiated, such project may be completed within three to five years.

BP&R Acquisition

In March 2021, we completed the acquisition of the FDA licensed plasma collection center and certain related assets from the privately held B&PR based in Beaumont, Texas, which specializes in the collection of hyper-immune plasma used in the manufacturing of KAMRHO (D) IV and IM products. Plasma-derived Anti-D products are being used for prophylaxis of hemolytic disease of newborns, and for the treatment of ITP. 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, for a total consideration of approximately $1.61 million, was consummated through Kamada Plasma LLC, a newly formed wholly owned subsidiary of the Company, which operates our plasma collection activity in the United States. The acquisition of B&PR's plasma collection center represented our entry into the U.S. plasma collection market. We are in the process of significantly expanding our hyperimmune plasma collection capacity by investing in this plasma collection center in Beaumont, Texas, while initiating a project to leverage our FDA license to establish a network of new plasma collection centers in the United States, with the intention to collect normal source as well as hyperimmune specialty plasma required for manufacturing of our other Proprietary IgG products including KAMRAB/KEDRAB as well as for some of the products included in our recently acquired products portfolio.

COVID-19

The global COVID-19 pandemic affected economic activity worldwide and led, among other things, 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. As a result of the COVID-19 pandemic, we have experienced a reduction in inbound and outbound international delivery routes, which have caused, delays in receipt of raw material and shipment of finished product. Our business activity and commercial operations were affected by these factors, and we have taken several actions to ensure our manufacturing plant remains operational with limited disruption to our business continuity. We increased our inventory levels of raw materials through our suppliers and service providers to appropriately manage any potential supply disruptions and secure continued manufacturing. In addition, we are actively engaging freight carriers to ensure inbound and outbound international delivery routes remain operational and identify alternative routes, if needed. We comply with the State of Israel mandates and recommendations with respect to work-force management and have taken several 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.

COVID-19 related disruption had various effect on our business activities, commercial operation, revenues and operational expenses. However, as a result of the actions taken, our overall results of operations for the year ended December 31, 2021 were not materially affected. While there is an evident trend of recovery from the pandemic due to the increased vaccination rate of the population, a number of factors including, but not limited to, continued demand for our commercial products, availability of raw materials, financial conditions of our customer, suppliers and services providers, our ability to manage operating expenses, additional competition in the markets that we compete in, 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 due to substantial uncertainty but may materially affect our business, financial condition, and results of operations. We assess the impact of COVID-19 in several possible scenarios and concluded that there are no uncertainties that may cast significant doubt on our ability to continue as a going concern or affect significantly on our liquidity.

Our Commercial Product Portfolio

Our commercial products portfolio includes our proprietary plasma-derived biopharmaceutical products in our Proprietary Products segment, which are marked and sold directly or through local distributers in the U.S., Canada, and additional approximately 30 markets worldwide, as well as licensed products, some of which are plasma-derived, which are marketed and sold by us in our Distribution segment in Israel.

Proprietary Products Segment

Our products in the Proprietary Products segment consist of plasma-derived protein and IgGs therapeutics derived from human plasma that are administered by injection or infusion. Such products include the recently acquired portfolio of four FDA approved products. We also manufacture anti-snake venom products from equine based serum.

Our Proprietary Products sales accounted for approximately 73%, 76% and 77% of our total revenues for the years ended December 31, 2021, 2020 and 2019, respectively. Historically, our leading product in the Proprietary Products segment was GLASSIA; however, as a result of the transition of GLASSIA manufacturing to Takeda which was completed during 2021, revenues from the sale of GLASSIA to Takeda decreased in 2021. Sales of GLASSIA (worldwide, including to Takeda), for the years ended December 31, 2021, 2020 and 2019, accounted for approximately 34%, 53% and 58% of our total revenues, respectively. Sales of GLASSIA to Takeda for further distribution in the U.S. market comprised approximately 25%, 49% and 54% of our total revenues for the years ended December 31, 2021, 2020 and 2019, respectively. In addition, during 2021 we recognized revenues of $5.0 million on account of a sales milestone due from Takeda. Revenues from sales of KEDRAB to Kedrion for further distribution in the U.S. market for the years ended December 31, 2021, 2020 and 2019, accounted for approximately 12%, 14% and 13% of our total revenues, respectively. For the year ended December 31, 2021, revenues from sales of the recently acquired portfolio of four FDA approved products (effective from November 22, 2021), accounted for approximately 5% of our total revenues. Sales of KAMRAB, KAMRHO (D) (IM and IV), the anti-snake venom, as well as our development stage Anti-SARS-CoV-2 IgG product accounted for the substantial balance of total revenues in the Proprietary Products segment for the years ended December 31, 2021, 2020 and 2019.

The following tables lists our Proprietary Products:

Product	Indication	Active Ingredient	Geography
KAMRAB/ KEDRAB	Prophylaxis of rabies disease	Anti-rabies immunoglobulin (Human)	USA, Israel, India, Thailand, El Salvador*, Bosnia***, Russia, Mexico*, Georgia*, Sri Lanka*, Ukraine, Turkey***, Poland***, South Korea***, Canada, Australia, Argentina***, Brazil***, and Chile***.
CYTOGAM	Prophylaxis of Cytomegalovirus (CMV) disease in kidney, lung, liver, pancreas, heart and heart/lung transplants	Cytomegalovirus Immune Globulin Intravenous (Human)	USA, Canada, and Qatar***
WINRHO SDF	Immune thrombocytopenic purpura (ITP) and suppression of rhesus isoimmunization (RH)	Rho(D) immunoglobulin (Human)	USA, Canada, Egypt, Hong Kong, Kuwait, Saudi Arabia, South Korea, Turkey, UAE, Uruguay, and Chile**
HEPAGAM B	Prevention of Hepatitis B recurrence liver transplants and post-exposure prophylaxis	Hepatitis B immunoglobulin (Human)	USA, Canada, Turkey, Israel, Saudi Arabia***, UAE, Bahrain***, and Kuwait*
VARIZIG	Post exposure prophylaxis of Varicella in high risk individuals	Varicella Zoster Immunoglobulin (Human)	USA, Canada, Belgium***, Kuwait***, Netherlands***, Sweden***, UAE***, Norway***, Denmark***, and Estonia***
GLASSIA (or Ventia/Respikam in certain countries)	Intravenous AATD	Alpha-1 Antitrypsin (Human)	USA, Canada**, Israel, Russia, Brazil*, Argentina, Uruguay**, South Africa***, Colombia**, Albania**, Kazakhstan**, and Costa Rica**
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 2021.
** Product was registered, but we have not yet started sales.
*** Product was marketed without registration.

Propriety Products

KamRAB/KEDRAB

KAMRAB is a hyper-immune plasma-derived therapeutic for prophylactic treatment against rabies infection that is administered to patients after exposure to an animal suspected of being infected with rabies. KAMRAB is manufactured at our manufacturing facility in Beit Kama, Israel from 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 29 million people worldwide receive a post-bite rabies vaccination. The U.S. Centers for Disease Control and Prevention (CDC) recommends that post-exposure prophylaxis (PEP) treatment for people who have never been vaccinated against rabies previously should always include administration of both Human Rabies Immuno Globulin (HRIG) and rabies vaccine. According to the CDC, the combination of HRIG and vaccine is recommended for both bite and non-bite exposures, regardless of the interval between exposure and initiation of treatment.

KamRAB has been sold by us in various markets outside the United States through local distributors since 2003 and is currently sold in 15 countries, including Canada where it received marketing approval in November 2018, in various South American markets through the Pan American Health Organization ("PAHO"), the specialized international health agency for the Americas, and in Australia in which it received marketing approval in August 2021.

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 (KAMRAB/KEDRAB and Anti-SARS-CoV-2)*." 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 for PEP against rabies infection, and in April 2018 KAMRAB was launched in the United States (under the trademark "KEDRAB").

In June 2021, the FDA approved a label update for KEDRAB, establishing the product's safety and effectiveness in children aged 0 to 17 years. The new updates to the KEDRAB label are based on data from the KEDRAB U.S. post marketing pediatric study, the first and only clinical trial to establish pediatric safety and effectiveness of any HRIG in the United States. 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. According to the Centers for Disease Control and Prevention data, no children in the United States treated with post-exposure prophylaxis have been reported to have had rabies between 2018 and April 2021, which supports the use of KEDRAB in children.

Our overall revenues from sales of KEDRAB to Kedrion during 2021, 2020 and 2019 were $11.9 million, $18.3 million and $16.4 million, respectively. The reduction of sales of KEDRAB to Kedrion during 2021 was a result of relatively higher level of inventory of product at Kedrion as of December 31, 2020, which was due to reduced KEDRAB sales by Kedrion during 2020 as a result of the effect of the COVID-19 pandemic. Sales of KEDRAB by Kedrion in the United States during 2021, 2020 and 2019 totaled $24.7 million, $23.7 million and $31.4 million, respectively. Based on information provided by Kedrion, these sales represent approximately 27%, 23% and 20% share of the relevant U.S. market in each of these years, respectively. The sales of KEDRAB by Kedrion during 2021 continued to be affected by the COVID-19 pandemic.

CYTOGAM

CYTOGAM (Cytomegalovirus Immune Globulin Intravenous (Human)) (CMV-IGIV) is indicated for prophylaxis of cytomegalovirus ("CMV") disease associated with the transplantation of the kidney, lung, liver, pancreas and heart. CYTOGAM, approved by the FDA in 1998, is the sole FDA-approved immunoglobulin (IgG) product for this indication, and was acquired by us from Saol in November 2021.

CYTOGAM is administered within 72 hours after transplantation and then at week 2,4,6,8,12 and 16 weeks after transplantation. The precise dosage is adjusted according to patient's weight. CMV seroprevalence in the US is estimated as 50-80% among adults. CMV is typically passed through direct personal contact. A seropositive status indicates exposure to the virus and development of antibodies against CMV. After initial infection, CMV establishes lifelong latency in the host. Immunocompetent individuals possess few defenses, which protect mostly from infection and clinical symptoms (cell-mediated immunity). Immunocompromised patients, such as transplant patients, are vulnerable to both de novo and reactivation of CMV. In solid organ transplants, seronegative recipients (R-) receiving seropositive organs (D+) have the highest risk of CMV infection and disease. CMV disease incidence in kidney recipients are 2%-19%, but over 25% in high-risk thoracic organ recipients. Lung transplant patients have the highest risk of CMV infection and disease. CYTOGAM can help to re-establish the natural immune function of transplant patients: it modulates and interacts with immune cells exerting a positive immunological balance. Investigational studies have shown that administration of CMV-IGIV is associated with neutralization of free CMV particles, opsonization, specific activation of the immune system, and immunomodulation.

In the U.S., there were more than 40,000 Solid Organ Transplants ("SOT") procedures performed during 2021. It is projected that number of transplant procedures will continue to grow at a rate of 6.5% over the next five years. Several available antivirals (acyclovir, valacyclovir, ganciclovir and valganciclovir) are being used and are considered efficient in the prevention and treatment of CMV infection. Those are considered standard of care for high-risk patients. As CMV infection in high-risk post-transplant patients can be severe and even life-threatening, we believe that administration of CYTOGAM together with the available antivirals can serve as a preferred option for preventing CMV disease, based on CMV hyperimmune clinical evidence to improve transplant outcomes in combination with antiviral therapy. We believe there is an under-usage of CYTOGAM to prevent CMV disease in SOT due to low awareness of its benefits when used with antiviral therapy for high-risk patients. We intend to promote the awareness for such benefits as we believe that increased awareness can support higher usage rates.

CYTOGAM is registered and sold in the United States and Canada. In addition, CYTOGAM is supplied on a named patient basis without registration in Qatar. We plan to leverage our existing international distribution network to explore the opportunities to register and commercialize the product in other territories. In addition, we may explore label expansion opportunities for the use of CYTOGAM in other indications.

We expect to receive FDA approval for the transfer of the ownership of the U.S. BLA for CYTOGAM during 2022. In addition, the technology transfer process for CYTOGAM manufacturing to our manufacturing facility in Beit Kama, Israel is well underway, and we expect to receive FDA approval for the manufacturing of CYTOGAM and initiate commercial manufacturing of the product in early 2023. Request for approval to transfer the Drug Identification Number ("DIN") was submitted in March 2022, and once approved, we expect to submit a request to transfer the registration of the product in other international countries as applicable. An approval for the marketing of CYTOGAM, manufactured at our manufacturing facility, in Canada is planned to be submitted during the second half of 2022.

WINRHO SDF

WINRHO SDF is a Rho(D) Immune Globulin Intravenous (Human) product indicated for use in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage in the treatment of non-splenectomies, for Rho(D)-positive children with chronic or acute immune thrombocytopenia (ITP), adults with chronic ITP, and children and adults with ITP secondary to HIV infection. WINRHO SDF is also used for suppression of Rhesus (Rh) Isoimmunization during pregnancy and other obstetric conditions in non-sensitized, Rho(D)-negative women. WINRHO SDF, approved by the FDA in 1995, was acquired by us from Saol in November 2021.

Immune thrombocytopenic purpura (ITP) is a blood disorder characterized by a decrease in the number of platelets - the cells that help blood clot. Recent findings suggest that nearly 20,000 children and adults are newly diagnosed with ITP each year in the United States. Rho(D) immunoglobulin can be an effective option for rapidly increasing platelet counts in patients with symptomatic ITP.

Hemolytic disease of the newborn (HDN) is a blood disorder in a fetus or newborn infant. In some infants, it can be fatal. During pregnancy, Red Blood Cells (RBCs) from the unborn baby can cross into the mother's blood through the placenta. HDN occurs when the immune system of the mother sees a baby's RBCs as foreign. Antibodies then develop against the baby's RBCs. These antibodies attack the RBCs in the baby's blood and cause them to break down too early. Rho(D) immunoglobulin is administered to pregnant women with Rh-negative women, as prophylactic therapy, to prevent the disease. Rh- negative blood type proportion differentiate from country to country and in the United States 15% of people are Rh-negative.

In the U.S. market WINRHO SDF is used almost solely as treatment of ITP, however due to an FDA black-box warning for Intravascular Hemolysis (IVH) issued in 2011, as well as the introduction of new ITP therapies, its sales in the U.S. market dropped significantly between 2011 to 2017 and have remained relatively flat since. The current use of WINRHO SDF in the U.S. market is for treatment of acute ITP in which it competes mainly with high-dose IVIG. We believe that as the only Rho (D) product positioned in the U.S. for ITP and given its advantage over IVIG in treatment of acute ITP, increasing awareness amongst treating physicians may support higher usage rates.

WINRHO SDF is currently registered and sold in 10 territories including the United States and Canada**,** as well as Egypt, Hong Kong, Kuwait, Saudi Arabia, South Korea, Turkey, the United Arab Emirates and Uruguay. . In ex-U.S. territories, the product is mainly used to treat HDN, and we plan to leverage our existing international distribution network to register and commercialize the product in other territories.

Request for the transfer of the ownership of the BLA for WINRHO SDF was submitted to the FDA in December 2021 and approval is expected in mid-2022. Request for approval to transfer the ownership of the DIN and approval for us to manufacture or have manufactured the product for marketing was submitted in March 2022, and once approved, we expect to submit a request to transfer the registration of the product in other international countries as applicable.

WINRHO SDF is manufactured by Emergent under a contract manufacturing agreement, which was assigned to us by Saol following the consummation of the acquisition. We expect to continue manufacturing the product with Emergent in the foreseeable future, while initiating in parallel a technology transfer project for transitioning the manufacturing of WINRHO SDF to our manufacturing facility in Beit Kama, Israel. The initiation of such technology transfer project is subject to executing an amendment to the manufacturing services agreement with Emergent covering the technology transfer related services and scope. We anticipate that once initiated, such project may be completed within three to five years.

Our KAMRHO (D) is a comparable product to WINRHO SDF and approved for similar indication. The two products are registered and distributed in different markets.

HEPAGAM B

HEPAGAM B is a hepatitis B Immune Globulin (Human) (HBIg) product indicated to both prevent hepatitis B virus (HBV) recurrence following liver transplantation in hepatitis B surface antigen positive (HBsAg- positive) patients and to provide post-exposure prophylaxis treatment. HEPAGAM B, which was approved by the FDA in 2006 for post-exposure prophylaxis and in 2007 as a prevention therapy, was acquired by us from Saol in November 2021.

Liver transplantation is the treatment of choice for patients with liver failure secondary to chronic hepatitis B. However, liver transplantation is complicated by the risk of recurrent hepatitis B virus infection, which significantly impairs graft and patient survival. Prevention of hepatitis B virus (HBV) reinfection includes use of antiviral therapy, with the addition of hepatitis B immune globulin. HBIG treatment is based upon the rationale that administered antibody will bind to and neutralize circulating virions, thereby preventing graft infection.

In the U.S. market HEPAGAM B is mostly used for post-transplant prophylaxis in which it competes with ADMA Biologics Inc.'s ("ADMA") Nabi-B product. Given the continued increase in liver transplants in the U.S. as well as several ex-U.S. countries, and with our planned direct marketing efforts we believe product usage may grow.

HEPAGAM B is registered and sold in five territories including the United States, Canada, Turkey, Israel, and the United Arab Emirates. In addition, HEPAGAM B is supplied on a named patient basis without registration in Saudi Arabia and Bahrain. Registration of HEPAGAM B in Saudi Arabia is currently on going.

Request for transfer of the ownership for the BLA of HEPAGAM B was submitted to the FDA in December 2021 and approval is expected in mid-2022. Request for approval to transfer the ownership of the DIN and approval for us to manufacture or have manufactured the product for marketing in Canada was submitted in March 2022, and once approved, we expect to submit a request to transfer the registration of the product in other international countries as applicable.

HEPAGAM B is manufactured by Emergent under a contract manufacturing agreement which was assigned from Saol following the consummation of the acquisition. We expect to continue manufacturing the product with Emergent in the foreseeable future, while initiating in parallel a technology transfer project for transitioning the manufacturing of HEPAGAM B to our manufacturing facility in Beit Kama, Israel. The initiation of such technology transfer project is subject to executing an amendment to the manufacturing services agreement with Emergent covering the technology transfer related services and scope. We anticipate that once initiated, such project may be completed within three to five years.

VARIZIG

VARIZIG [Varicella Zoster Immune Globulin (Human)] is a product that contains antibodies specific for the Varicella zoster virus, and it is indicated for post-exposure prophylaxis of varicella (chickenpox) in high-risk patient groups, including immunocompromised children, newborns, and pregnant women. VARIZIG is intended to reduce the severity of chickenpox infections in these patients. The U.S. Centers for Disease Control (CDC) recommends VARIZIG for post-exposure prophylaxis of varicella for persons at high-risk for severe disease who lack evidence of immunity to varicella. VARIZIG, approved by the FDA in 2013, is the sole FDA-approved IgG product for this indication, and was acquired by us from Saol in November 2021.

Varicella-zoster virus (VZV) causes varicella (chicken pox) and herpes zoster (shingles). Varicella is a common childhood illness. Herpes zoster is caused by VZV reactivation. The incidence of herpes zoster increases with age or immunosuppression. Individuals at highest risk of developing severe or complicated varicella include immunocompromised people, preterm infants, and pregnant women. Varicella zoster immune globulin (human) (VARIZIG) is recommended by the CDC for post-exposure prophylaxis to prevent or attenuate varicella-zoster virus infection in high-risk individuals. VARIZIG may help these vulnerable patients to be defended against serious disease from varicella exposure. It has been demonstrated that post-exposure administration of VARIZIG was associated with low rates of varicella in high-risk patients.

VARIZIG is registered and sold in the United States and Canada. In addition, VARIZIG is supplied on a named patient basis or through a tender in Belgium, Kuwait, Netherlands, Sweden, the United Arab Emirates, Norway, Denmark and Estonia. In Latin America countries, we are participating in a tender for the potential distribution of VARIZIG by the Pan American Health Organization (“PAHO”), which also serves as Regional Office for the Americas of the World Health Organization (“WHO”).

Request for transfer of the ownership for the BLA for VARIZIG was submitted to the FDA in December 2021 and approval is expected in mid-2022. Request for approval to transfer the ownership of the DIN and approval to manufacture or have manufactured the product for marketing in Canada was submitted in March 2022.

VARIZIG is manufactured by Emergent under a contract manufacturing agreement which was assigned from Saol following the consummation of the acquisition. We expect to continue manufacturing the product with Emergent in the foreseeable future, while initiating in parallel a technology transfer project for transitioning the manufacturing of VARIZIG to our manufacturing facility in Beit Kama, Israel. The initiation of such technology transfer project is subject to executing an amendment to the manufacturing services agreement with Emergent covering the technology transfer related services and scope. We anticipate that once initiated, such project may be completed within three to five years.

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 a single weekly intravenous infusion.

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. We believe that the primary reasons for this significant gap 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. We expect diagnosis of AATD to continue to increase going forward as awareness of AATD increases. Based on a market analysis report from 2020, the estimated annual growth rate of currently approved AATD therapies in the U.S. and the five largest European countries is approximately 6-8%

According to the Centers for Medicare and Medicaid Services, published payment allowance limits for Medicare part B, the average sale price, as of January 2022, of 10 mg of GLASSIA is $4.982, resulting in an annual cost of between $80,000 and $120,000 per each 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.

GLASSIA was the first FDA-approved liquid AAT, which is ready for infusion and does not require reconstitution and mixing before infusion, 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- infuse at home.

Currently, GLASSIA is registered in eleven countries, and is sold in four 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. According to our agreement with Takeda (See "— Strategic Partnerships — Takeda (Glassia)."), 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 clinical study report is being completed and is anticipated to be submitted to the FDA in the first half of 2022. The second Phase 4 efficacy study was initiated during 2016 and was terminated two years after initiation based on the Data and Safety Monitoring Board's recommendation due to very low recruitment rates. During 2019, Takeda submitted a revised Phase 4 protocol to the FDA. Following several interactions with the FDA with respect to the Phase 4 efficacy study requirements, Takeda decided not to continue to pursue the study.

Through 2021, we marketed GLASSIA in the United States through our partnership with Takeda. Sales to Takeda accounted for approximately 25%, 49% and 54% of our total revenues in the years ended December 31, 2021, 2020 and 2019, respectively. Takeda completed the technology transfer of GLASSIA manufacturing during 2021, received FDA approval for its own manufacturing and initiated its own production of GLASSIA for the U.S. market, Accordingly, based on the agreement between the companies, upon initiation of sales of GLASSIA manufactured by Takeda, it will, commencing 2022, 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.

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KAMRHO (D)

KAMRHO (D), similar to WINRHO SDF, 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 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).

We have completed the registration process for Kam Rho (D) in several countries and we currently sell it in eight countries, including Israel, as well as countries in Latin America, Asia, Africa and Eastern Europe.

Snake Bite Antiserum

Our snake bite antiserum product is used for the treatment of people who 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 in the Israeli market for *Vipera palaestinae* and *Echis coloratus* snake bites.

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 sale of our snake bite antiserum to the IMOH is conducted on the basis of a tender, unless the IMOH grant an exemption from the tender. Our tender exemption from the IMOH was recently extended until 2025 and we have signed a new agreement with the IMOH.

Distribution Segment

Our Distribution segment is comprised of marketing and 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, market, sell and distribute them to local HMOs, hospitals and pharmacists. Our Distribution segment sales accounted for approximately 27%, 24% and 23% of our total revenues for the years ended December 31, 2021, 2020 and 2019, respectively. Our primary products in the Distribution segment include pharmaceuticals for critical care 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 73%, 76% and 62% of total revenues in the Distribution segment for the years ended December 31, 2021, 2020 and 2019, respectively. Sales of IVIG accounted for approximately 20%, 19% and 14% of our total revenues for the years ended December 31, 2021, 2020 and 2019, 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. We have recently added two additional products to the agreement, bringing the total number of products in the portfolio to eight. 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 received FDA approval. Following receipt of the European Medicines Agency ("EMA") marketing approval by Alvotech, the remaining seven products included in the agreement are, subject to approval by the IMOH, expected to be launched in Israel during the years 2023-2028. In addition, in January 2021, we announced our entering into agreements with two undisclosed international pharmaceutical companies to commercialize three additional 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 2026. The two pharmaceutical companies will maintain development, manufacturing and supply responsibilities for these three products.

Based on the projected list price reduction due to increased competition as a result of the launch of the biosimilar products, and anticipated market penetration potential, we estimate the potential aggregate peak revenues from the sale of all eleven products, achievable within several years of launch, to be more than $40 million annually.

The following table sets forth our primary products in the 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
RUPAFIN	Symptomatic treatment of Allergic rhinitis and Urticaria	Rupatadine
Immunoglobulins		
IVIG	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 CP	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	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
VIVOTIF	Immunization against disease caused by Salmonella Typhi	Typhoid vaccine live oral
Metabolic Disease		
PROCYSBI	nephropathic cystinosis in adults and children 1 year of age and older	Cysteamine Biartrate
LAMZEDE	Treatment of alpha-mannosidosis	Velmanase alfa
Oncology		
ELIGARD	Management of advanced prostate cancer	Leuprolide acetate

Plasma Collection

As part of our strategy of evolving into a fully integrated specialty plasma company, we established Kamada Plasma LLC, a newly formed wholly owned subsidiary, which operates our plasma collection activity in the United States. In March 2021, we completed the acquisition of the FDA licensed plasma collection center and certain related assets from 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.

The acquisition of B&PR's plasma collection center represented our entry into the U.S. plasma collection market. We intend to leverage this acquisition to enhance our self-sufficiency in terms of plasma supply needs as well as generate sales from commercialization of collected normal source plasma. We are in the process of significantly expanding our hyperimmune plasma collection capacity by investing in the acquired plasma collection center in Beaumont, Texas, while initiating a project to leverage our FDA plasma collection license to establish a network of new plasma collection centers in the United States, commencing in 2022, with the intention to collect normal source plasma for sale to other plasma-derived manufacturers, as well as hyperimmune specialty plasma required for manufacturing of our Proprietary products including KAMRAB/KEDRAB as well as for some of the products included in our recently acquired products portfolio.

Our Development Product Pipeline

Our research and development activities include conducting pre-clinical and clinical trials and other development activities for our Propriety pipeline products, improving existing products and processes, conducting development work at the request of regulatory authorities and strategic partners, as well as communicating with regulatory authorities in regard to our commercial products as well as our clinical programs. We incurred approximately $11.4 million, $13.6 million and $13.1 million in research and development expenses in the years ended December 31, 2021, 2020 and 2019, respectively.

We are in various stages of pre-clinical and clinical development of new product candidates for our Proprietary Products segment.

Inhaled Formulations of AAT for AATD

We are in the process of clinical development of an inhaled formulation 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 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 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, improving the patient's quality of life and reducing medical costs.

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, in once daily session.

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 an inhaled formulation of AAT through inhalation results in greater dispersion of AAT to the target lung tissue, including the lower lobes and lung periphery. Accordingly, the inhaled formulation of AAT requires a significantly lower therapeutic dose, and we believe it 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.

Because of the smaller amount of AAT dose 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.

We conducted a double-blind randomized placebo controlled 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 twice daily treatment of Inhaled AAT or equivalent dose of placebo for 50 consecutive weeks. The primary endpoint of 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 additional exacerbation measures, lung function, lung density measured by 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 after 50 weeks. A 20% difference between the two groups was required to prove efficacy and was considered clinically meaningful, allowing the decision to prescribe the 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) which was 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 meetings conducted with the European rapporteur and co-rapporteur, we performed several post hoc analyses. Results of the post hoc analyses indicated 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 effect for one year:

- 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 a Phase 2 trial 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 daily inhalation of 80 mg or 160 mg of human AAT or placebo 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 in the study 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 sufficient 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, 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.

Following that feedback from the FDA and the EMA we have initiated our Phase 3 InnovAATe study and 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 continued slowly in 2021 due to the impact of COVID-19 pandemic on healthcare systems. During the first half of 2022 we plan to open up to six additional sites in Europe in order to expand the recruitment efforts for this study. The first of the additional sites was opened during the second part of February 2022.

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 conducted a subsequent HFS to support improved use regimen of the product and the improved use regimen was implemented in the InnovATTe study.

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.

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

In response to the 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 IVIG 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.

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 the product. 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 occurred for 84 days. In March 2021, we announced top-line results for the Phase 1/2 clinical trial, according to which symptoms improvement was observed in 11 of the 12 patients within 24 to 48 hours from treatment. Seven patients were discharged from the hospital at or before day 5 post-treatment and the remaining four patients were discharged by day 9. Following the infusion of the product anti-SARS CoV-2 IgG levels in the plasma of all patients increased. Our Anti-SARS-CoV-2IgG product demonstrated a favorable safety profile, and there were no infusion-related reactions or adverse events considered related to study drug. There were two serious adverse events in the study, both were considered not related to the study drug. One patient died on day 37 post treatment due to complications from COVID-19. Another patient was diagnosed post-discharge with pulmonary embolism on day 7 of the study. The patient was re-hospitalized, treated with anticoagulation therapy, recovered within two days, and was subsequently discharged from the hospital.

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 manufactured the product, which was 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 in the U.S. The order, supplied during 2021, was sufficient to treat approximately 500 hospitalized patients and generated approximately $3.9 million in revenue in 2021. The IMOH has initiated a multi-center clinical study through which our product is being administered. Based on information provided by the IMOH, the recruitment to this study was completed and the IMOH is in the process of analyzing its results. The supply of the product to the IMOH was not extended beyond the initial order.

Given the increased vaccination rate of the population as well as approvals of monoclonal antibodies for COVID-19, we are currently evaluating the market potential of this product, and the continuation of its development program.

Recombinant AAT

We are advancing the development of recombinant human Alpha 1 Antitrypsin ("rhAAT") product. To ensure the success of this project, we have developed analytical tools (physicochemical, biochemical, and biological assays) that support the selection and characterization of the product. We are working with Cellca a CDMO located in Germany, part of Sartorius Stedim BioTech Group, to pursue the cell line development of the rhAAT in Chinese Hamsters Ovaries with the goal of developing high productivity and superior quality product. During 2021 we completed the final stages of clones selection and initiated in vitro and in vivo studies testing the biological activity of the product in various models. The pre-clinical work is performed in collaboration with relevant institutions in Europe and the US.

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.

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.

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 that includes three main agreements: (1) an exclusive manufacturing, supply and distribution agreement, pursuant to which until November 2021 we manufactured 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 supplies us with fraction IV plasma, a plasma derivative, produced by Takeda, as discussed under "— Manufacturing and Supply — Raw Materials — *Plasma derived Fraction IV paste for GLASSIA manufacturing* Other than with respect to plasma-derived AAT administration by IV, we retain all rights, including distribution rights, to any other form of AAT administration, including Inhaled AAT for AATD.

The agreements were originally executed with Baxter in August 2010. During 2015, Baxter assigned all its rights under the agreements 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 agreements were assigned to Shire. In January 2019, Takeda completed its acquisition of Shire, and all rights under the agreement transferred to Takeda.

Exclusive Manufacturing, Supply and Distribution Agreement

Pursuant to the exclusive manufacturing, supply and distribution agreement, as amended from time to time, Takeda was obligated to purchase a minimum amount of GLASSIA per year until the end of 2021. Under the agreement, Takeda is also obligated to fund required Phase 4 clinical trials related to GLASSIA up to a specified amount, and if the costs of such clinical trials are in excess of this amount, we agreed to fund a portion of the additional costs. We also undertook to reimburse Takeda for its GLASSIA marketing efforts up to a limited amount during the years 2017-2020.

In November 2021, pursuant to the technology license agreement described below, Takeda completed the technology transfer of GLASSIA manufacturing, and initiated its own production of GLASSIA for the U.S. market. Accordingly, we completed the supply of GLASSIA to Takeda and, while for a certain period of time we are still an approved supplier of the product, we do not anticipate continuing to manufacture and supply GLASSIA to Takeda under the exclusive manufacturing, supply and distribution agreement.

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 the total aggregate milestone payments under the agreement ($20 million). The terms of the final sales-based milestone of $5 million due under the license agreement were amended under an amendment to the license agreement entered into in March 2021, and we recognized this milestone during the first quarter of 2021.

During the fourth quarter of 2021 Takeda received an approval from Health Canada for the marketing and distribution of Glassia in Canada.

Pursuant to the technology license agreement, following the initiation of GLASSIA manufacturing by Takeda, and commencing during 2022, 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.

Pursuant to the amendment to the license agreement entered into in March 2021, upon completion of the transition of GLASSIA manufacturing to Takeda, we will transfer to Takeda the GLASSIA U.S. BLA, in consideration of an additional $2 million payment from Takeda, payable upon acknowledgment by the FDA of effecting such transfer. The notice of transfer of the BLA to Takeda was submitted to the FDA during the fourth quarter of 2021 and FDA's acknowledgment is expected to be received during the first half of 2022.

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; or (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. 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 (KAMRAB/KEDRAB and Anti-SARS-CoV-2)

KAMRAB/KEDRAB

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 provided for exclusive cooperation on completing the clinical development, and marketing and distribution of our anti-rabies immunoglobulin, 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. Pursuant to the agreement, 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, we and Kedrion 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 April 2018, following the receipt of an FDA marketing authorization, we launched KEDRAB in the United States. For more information about the product see above "Item 4. Information on the Company — *Proprietary Products Segment* — Our Commercial Product Portfolio — *Propriety Products — KAMRAB/KEDRAB*".

The term of the agreement is for six years commencing on the date by which KEDRAB U.S. launch was feasible (i.e., until March 2024). Kedrion has an option to extend the term by two additional years (i.e., until March 2026). In addition to customary termination provisions, Kedrion 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 BLA 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.

During April 2020, we announced a term sheet covering 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. The parties agreed not to formalize this engagement in a definitive agreement until final decision on the progression of this development program.

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 Royalty Period"). During the PARI Royalty 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 also 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 currently manufacture five of our proprietary plasma-derived commercial products in this facility: GLASSIA, KAMRAB/KEDRAB, KAMRHO(D)IM, KAMRHO(D)IV and two types of the snake bite antiserum product. We expect to complete the technology transfer process for CYTOGAM, which we acquired from Saol in November 2021, and initiate commercial manufacturing of the product at our facility by early 2023. 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 each year we have routine maintenance shutdowns of our plant, which may last up to a few weeks. In addition, we periodically invest in upgrading infrastructures and adjusting capacity needs.

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, November 2018, and December 2020 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.

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.

Three of the products that we acquired from Saol in November 2021, HEPAGAM B, VARIZIG and WINRHO SDF, are manufactured by Emergent under a manufacturing services agreement we assumed as part of the acquisition of the portfolio from Saol. Under the agreement, Emergent serves as the exclusive manufacturer of the products in certain jurisdictions. The manufacturing services are performed at Emergent's facilities in Winnipeg, Canada. The agreement is in effect until September 27, 2027 and may be terminated without cause by us upon at least two years advance notice or by Emergent upon at least three years advance notice or by us immediately in the event of a manufacturing failure (as defined in the agreement). We expect to continue manufacturing these products with Emergent in the foreseeable future, while initiating in parallel a technology transfer project for transitioning the manufacturing of these products to our manufacturing facility in Beit Kama, Israel. The initiation of such technology transfer project is subject to executing an amendment to the manufacturing services agreement with Emergent covering the technology transfer related services and scope. We anticipate that once initiated, such project may be completed within three to five years.

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, 2021, 2020 and 2019, we incurred $16.7 million, $22.9 million and $31.5 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 feasibility and negotiating 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), and for the products recently acquired from Saol, CYTOGAM, HEPAGAM B, VARIZIG and WINRHO SDF. 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. The agreement is being renewed every three years, and the parties agree on quantity and pricing terms in each renewal period.

CMV hyper-immune plasma for the manufacturing of CYTOGAM is supplied by CSL Behring Ltd. under a Plasma Supply Agreement for CMV Hyperimmune Plasma, dated August 2019, by and between CSL Plasma, Inc. and Saol which was assigned to us pursuant to the product acquisition. Pursuant to the manufacturing services agreement, Emergent (see above— "Manufacturing and Supply"), is currently responsible for securing the hyper-immune plasma from different plasma suppliers for the manufacturing of HEPAGAM B, VARIZIG and WINRHO SDF. As part of our plans to transition the manufacturing of HEPAGAM B, VARIZIG and WINRHO SDF to our manufacturing plant in Beit Kama, Israel, we intend to enter into long term plasma supply agreements with Emergent' s current plasma suppliers and additional plasma suppliers in order to secure the plasma supply needed for the manufacturing of these products.

For information related to our internal plasma collection capabilities, see above "*Plasma Collection*"

Marketing and Distribution

We distribute our Proprietary products in more in 30 countries world-wide including the U.S., Canada, Russia, Argentina, Israel, India, Turkey, Australia and several other countries in Latin America, Asia, the Middle East and North Africa. In general, we distribute our products in these markets through strategic partners (e.g.,. Takeda and Kedrion in the U.S. market) and local distributers. We typically receive orders for our products and receive requests for participation in tenders for the supply of our products from our existing distributors as well as from new potential distributors.

Through 2021, we sold GLASSIA to Takeda for further distribution in the U.S. market and we sell the product to other distributors in non-U.S. countries. We sell KEDRAB to Kedrion for distribution in the U.S. market and sell KAMRAB and KAMRHO (D) to other distributers in non-U.S. countries. In the Israeli market, we sell and distribute GLASSIA, KAMRAB/KEDRAB and KAMRHO (D) independently to local HMOs and medical centers, or through a logistic partner company that specializes in the supply of equipment and pharmaceuticals to healthcare providers, and in addition we sell our anti-snake venom to the IMOH.

We distribute CYTOGAM, HEPAGAM B, VARIZIG and WINRHO SDF in the U.S. market directly to wholesalers and local distributors, through our wholly-owned US subsidiary, Kamada Inc. Through the term of the transition services agreement, we currently rely on Saol to manage and oversee the U.S. distribution of these products. In preparation for assuming all distribution responsibilities, Kamada Inc. is in the process of engaging a local U.S. third-party logistics (3PL) provider, which is expected to provide complete order to cash services. For the distribution of our products in the U.S. market, we are also responsible for marketing activities, price determination, provision of rebates and credits as well as mandatory pricing reporting requirements. We distribute these products in non-U.S. countries, primarily Canada, the Middle East and North Africa ("MENA"), through local distributors.

We intend to leverage our existing strong international distribution network to expand the sales of CYTOGAM, HEPAGAM B, VARIZIG and WINRHO SDF to existing markets we currently operate in and furthermore, we intend to explore the expansion of sales of our products, primarily GLASSIA and KAMRAB/KEDRAB to the new international markets we assumed following the acquisition of the new product portfolio, primarily in the MENA region.

Outside the U.S. market, our distributors, sell our products 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 distributors, our existing relationship does not guarantee additional orders in these tenders. The decisive parameter is generally the price proposed in the tender. The distributor purchases products 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 products in the relevant country, if permitted. 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 several 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.

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.

To secure supply of our products in the Distribution segment, we enter into supply and distribution agreements with the product manufacturers, pursuant to which we undertake to register the products with the IMOH, acquire certain quantity of products and act as the product distributor in the Israeli market. We work closely with those suppliers to develop annual forecasts, but these forecasts usually do not obligate our suppliers to provide us with their products.

Customers

For the year ended December 31, 2021, sales to our three largest customers, Takeda, Kedrion and Clalit Health Services, an Israeli HMO, accounted for 31%, 12% and 12%, respectively, of our total revenues. For the year ended December 31, 2020, sales to our three largest customers, Takeda, Kedrion and Clalit Health Services, 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 accounted for 54%, 13% and 11%, respectively, of our total revenues.

Historically, Takeda and Kedrion have been our major customers in the Proprietary Products segment. Our other key customers in the Proprietary Products segment includes PAHO and our distributors in Argentina, Russia, Thailand, India, Brazil, Canada and other territories as well as HMOs and medical centers in Israel. Following the assumption of the sales and distribution responsibilities for CYTOGAM, HEPAGAM B, VARIZIG and WINRHO SDF. our core customers list will be increased by eight U.S. based wholesalers, two Canadian customers and several distributors in other territories, mainly in the MENA region. These arrangements are further described above under "— Marketing and Distribution."

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

Competition

The worldwide market for pharmaceuticals in general, and biopharmaceutical and plasma products in particular, has undergone in recent years 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 Kedrion in the United States has strengthened our KEDRAB competitive positioning in the market. The recent acquisition of Biotest by Grifols and the recently announced potential merger between Kedrion and BPL might have an effect on competition landscape.

In addition, we face potential competition from other pharmaceutical companies who develop and market non-plasma derived products that are approved for similar indications as our Proprietary products.

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.

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 in the United States market, but the product is primarily sold in Europe and not currently sold in significant quantities in the United States. BPL is currently in clinical development of an anti-rabies product for the U.S. market. 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 immunoglobulin and may potentially be significantly cheaper, and as such may result in the future loss of market share of KAMRAB/KEDRAB.

CYTOGAM. To our knowledge, CYTOGAM is the only plasma derived CMV IgG product approved in the US and Canada. Based on available public information, the FDA approved antiviral drugs for the prevention of CMV infection and disease, Letermovir (Prevymis), developed by Merck & Co., and for treatment of refractory infection or disease Maribavir (Livtencity), developed by Takeda, and may result in the loss of market share for CYTOGAM. Currently, treatment guidelines state that combination therapy with standard antiviral can be considered for certain solid organ transplant recipients. The most commonly used antivirals are: Ganciclovir (Cytovene-IV Roche), Valgnciclovir (Valcyte Roche) and Valacyclovir (Valtrex GSK). Patients treated with such antivirals for a long time can develop resistance and will require a second line treatment such as Foscarnet (Foscavir Pfizer). In Europe and few ROW markets Biotest AG sells a competing CMV IgG product.

WINRHO SDF. In the United States, WINRHO SDF competes with corticosteroids (oral prednisone or high-dose dexamethasone) or IVIG (Grifols, CSL and Takeda are the main manufacturers in the U.S.) as first line treatment of acute ITP.IVIG has similar efficacy to WINRHO SDF, and ITP is a labeled indication. Rhophylac (CSL Behring) is also approved for ITP treatment, but we believe it is mostly used for Hemolytic Disease of the Newborn (HDN), due to its comparatively small vial size. For HDN indication, the market is usually led by tenders, where key indicators are registration status and price, and the main multiple competitors in Canada and ROW countries are RhoGAM (Kedrion), Hyper RHO (Grifols) and Rhophylac (CSL Behring) and our KAMRHO (D).

HEPAGAM B. HEPAGAM B is the only approved HBIG with an on-label indication for Liver Transplants in the United States. To our understanding, HEPAGAM B holds the majority market share for the indication, while another HBIG (Nabi-B marketed by ADMA) is being used off-label by some medical centers for the indication. In recent years the duration of treatment has been reduced by physicians. New generation antivirals are considered effective for preventing HBV reactivation post-transplant, reducing HBIG use. Post-exposure prophylaxis (PEP) indication in the United States is covered almost totally by Nabi-B (ADMA) and HyperHEP (Grifols). In Canada, the main competition in national tenders is HypeHEP. In ROW countries, such as Turkey, Saudi-Arabia and Israel, HEPATECT CP (Biotest AG) represents the main competition.

VARIZIG. In the United States, incidence of Varicella Zoster Virus ("VZV") infection has decreased significantly since the introduction of the varicella vaccine in 1995. Two vaccines containing varicella virus are licensed for use in the United States. Varivax is the single-antigen varicella vaccine. ProQuad is a combination measles, mumps, rubella, and varicella (MMRV) vaccine. Although the use of the vaccine has reduced the frequency of chickenpox, the virus has not been eradicated. Moreover, incidence of Herpes Zoster, also caused by VZV, is increasing among adults in the United States. Suboptimal vaccination rates contribute to outbreaks and increased risk of VZV exposure. Immunocompromised population and other patient groups are at high risk for severe varicella and complications, after being exposed to VZV. To our knowledge, VariZIG is the only plasma-derived IgG product approved in the US and Canada for its indication. It is recommended by the Centers for Disease Control (CDC) for post-exposure prophylaxis of varicella for persons at high risk for severe disease who lack evidence of immunity to varicella. In ROW markets, several plasma derived competitor products are available, such as VARITECT (Biotest AG) and others.

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 selling both products in the United States, and 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, there are several other competitors in pre-clinical and clinical stage such as Inhibrx, Mereo, PH Pharma, Centessa and Vertex Pharmaceuticals, all of which have clinical stage programs for new medications for treatment of AATD lung disease. Based on available public information, 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. Mereo, a UK based company, is in phase 2 development of MPH-966 as an oral neutrophil elastase inhibitor being explored for the potential treatment of AATD. PH Pharma has a similar oral anti elastase, PH-201 entering phase 2 development. Vertex, a Boston, MA headquartered company, is in pre-clinical development of 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. Clinical development of the corrector candidate VX-864 has been discontinued. Centessa pharma is in phase I clinical development of another corrector candidate. 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).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.

KAMRHO(D). KAMRHO(D) is a similar product to WINRHO SDF. While the two products are not currently registered in similar markets, they face similar competition in the markets in which they are registered. See WINRHO SDF above for information regarding competition.

Distribution Segment

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 strong 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, 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, including required CMC sections, 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, with all the required information;

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. The Sunshine Act requirements were expanded in January 2021 to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists & anesthesiologist assistants, and certified nurse-midwives as covered recipients. 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.

On November 27, 2020, the U.S. Trade Representative submitted a proposal to withdraw these drugs and medical devices identified by the FDA from U.S. commitments under the World Trade Organization Government Procurement Agreement (WTO GPA). On April 20, 2021, President Joe Biden ultimately withdrew this proposal. The withdrawal of this proposal allows the U.S. government to continue purchasing foreign-made drugs and medical devices as permitted under the Trade Agreements Act, and effectively counter's President Trump's August 2020 Executive Order directing the government to purchase domestically-produced essential drugs and medical devices. However, on January 25, 2021, President Joe Biden issued the Executive Order on Ensuring the Future Is made in All of America by All of America's Workers (Executive Order 14005) to maximize the use of goods, products, materials produced in, and services offered in the United States, which may affect FDA-related products. The full effect of the Executive Order and the withdrawal of the WTO proposal on our commercial operations and results of operations cannot currently be 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, Former 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 the Former President Donald Trump has vowed to repeal the healthcare reform law. On January 20, 2017, the Former 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, the Former 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, 2021, we owned for use within our field of business twelve 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, three pending PCT 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 CYTOGAM, GLASSIA, HepaGam, KAMRAB, KEDRAB, KAMADA, KamRHO, KamRHO-D, Rebinolin, RESPIKAM, RESPIRA, VariZIG and WinRho. Regarding the trademarks of CYTOGAM, WinRho, Hepagam and VariZIG we are in a process of transferring such trademarks to be registered in our name.

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 originally covered 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. Pursuant to a new area outline approved by the Israel Lands Administration, the covered area was reduced to 14,880 square meters. 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.

In addition, we lease approximately 2,200 square meters of a building located in the Kiryat Weizmann Science Park in Rehovot, Israel. This property houses our head office, research and development laboratory and additional departments such as clinical operations, medical, regulatory compliance, sales and marketing and business development. We sublease approximately 500 square meters of such premises to a third-party lessee.

As part of the acquisition of the FDA licensed and certain related assets from the privately held B&PR, we acquired a 237 square meters facility in Beaumont, TX, which we use as a plasma collection center. In addition, during 2021, and in preparation of the establishment of our U.S. commercial operations, we leased a two room office facility within a shared office facility in Hoboken, NJ.

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
KI Biopharma LLC	Delaware, USA
Kamada Inc.	Delaware, USA
Kamada Plasma LLC	Delaware (wholly owned by Kamada Inc.), USA
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 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, 2021, 2020 and 2019 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 vertically integrated global biopharmaceutical company, focused on specialty plasma-derived therapeutics, 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 as well as our manufacturing and development expertise in the plasma-derived and biopharmaceutical markets.. We operate in two segments: the Proprietary Products segment, which includes our plasma-derived biopharmaceuticals products including the following six FDA-approved products KEDRAB, CYTOGAM, HEPGAM B, VARIZIG, WINRHO SDF and GLASSIA that we market in 30 countries; 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 Commercial Activities

In November 2021, we acquired a portfolio of four FDA approved plasma-derived hyperimmune commercial products – CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF. The combined annual global revenue of the acquired portfolio in 2021 was approximately $41.9 million, of which our revenue was approximately $5.4 million and represents the sales generated from the date of consummation of the transaction through December 31, 2021. Approximately 75% and 21% of the annual sales of the acquired portfolio generated in the U.S. and Canada, respectively.

In addition to the recently acquired products portfolio, our Proprietary products includes GLASSIA, KAMRAB/KEDRAB, KAMRHO (D) IM and IV, as well as two types of anti-snake venom derived from equine plasma.

We market GLASSIA in the United States through a strategic partnership with Takeda. Our 2021 revenues from the sale of GLASSIA to Takeda totaled $26.2 million, as compared to $64.9 million and $68.1 million during 2020 and 2019, respectively. In addition, during 2021 we recognized as revenues $5.0 million on account of a sales milestone due from Takeda. The decrease in GLASSIA sales to Takeda in 2021 is associated with the completion of the transition of the product manufacturing to Takeda. Commencing in 2022, Takeda will pay royalties, on sales of GLASSIA manufactured by Takeda, 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. We expect 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 2021 was $7.6 million, as compared to $5.5 million and $5.5 million during 2020 and 2021, respectively.

We market KAMRAB in the United States under the trademark "KEDRAB" through a strategic distribution and supply agreement with Kedrion. Our 2021 revenues from sales of KEDRAB to Kedrion totaled $11.9 million as compared to $18.3 million and $16.4 million during 2020 and 2019, respectively. The reduction of sales of KEDRAB to Kedrion during 2021 was a result of relatively higher level of inventory of product at Kedrion as of December 31, 2020, which was due to reduced KEDRAB sales by Kedrion during 2020 as a result of the effect of the COVID-19 pandemic.

Our 2021 revenues from the sales of the remaining Proprietary products, including KAMRAB (outside the U.S. market), KAMRHO (D) IM and IV, the anti-snake venom, as well as our development stage Anti-SARS-CoV-2 IgG product totaled $18.4 million, as compared to $11.2 million and $7.1 million during 2020 and 2019, respectively.

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 the plasma-derived products sales represented approximately 84%, 89% and 81% of our Distribution segment revenues for the years ended December 31, 2021, 2020 and 2019, respectively. Over the past several years we continued to extend our Distribution segment products portfolio to non-plasma derived products, including recently entering into an agreement with Alvotech and two additional entities for the distribution in Israel of eleven different biosimilar products which, subject to EMA and subsequently IMOH approvals, are expected to be launched in Israel between the years 2022 and 2028. We estimate the potential aggregate maximum revenues, achievable within several years of launch, generated by the distribution of all eleven biosimilar products to be in more than $40 million annually.

In March 2021, we completed the acquisition of the FDA licensed plasma collection center and certain related assets from 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. We are in the process of significantly expanding our hyperimmune plasma collection capacity by investing in this plasma collection center in Beaumont, Texas, and initiated a project to leverage our FDA license to establish a network of new plasma collection centers in the United States, with the intention to collect normal source as well as hyperimmune specialty plasma required for manufacturing of our other Proprietary products including KAMRAB/KEDRAB as well as for some of the products included in our recently acquired products portfolio.

In addition to our commercial operation, we invest in research and development of new product candidates, including our leading investigational product Inhaled AAT for AATD, for which we are continuing to progress the InnovAATe clinical trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial, as well as several other product candidates. For additional information regarding our research and development activities, see "— *Our Development Product Pipeline*."

We currently expect to generate fiscal year 2022 total revenues in a range of $125 million to $135 million which would represent a 20% to 30% growth compared to fiscal year 2021. We also anticipate generating EBITDA, during 2022, at a rate of 12% to 15% of total revenues, representing more than 2.5x of the EBITDA for the year ended December 31, 2021.

COVID-19 Pandemic Effects

The global COVID-19 pandemic affected economic activity worldwide and led, among other things, 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. As a result of the COVID-19 pandemic, we've experienced a reduction in inbound and outbound international delivery routes, which have caused, delays in receipt of raw material and shipment of finished product. Our business activity and commercial operations were affected by these factors, and we have taken several actions to ensure our manufacturing plant remains operational with limited disruption to our business continuity. We increased our inventory levels of raw materials through our suppliers and service providers to appropriately manage any potential supply disruptions and secure continued manufacturing. In addition, we are actively engaging freight carriers to ensure inbound and outbound international delivery routes remain operational and identify alternative routes, if needed. We comply with the State of Israel mandates and recommendations with respect to work-force management and we have taken several precautionary health and safety measures to safeguard our employees continue to monitor and assess orders issued by the State of Israel and other applicable governments to ensure compliance with evolving COVID-19 guidelines.

COVID-19 related disruption had various effect on our business activities, commercial operation, revenues and operational expenses. However, as a result of the actions taken, our overall results of operations for the year ended December 31, 2021 were not materially affected. While there is an evident trend of recovery from the pandemic due to the increased vaccination rate of the population, a number of factors including, but not limited to, continued demand for our commercial products, availability of raw materials, financial conditions of our customer, suppliers and services providers, our ability to manage operating expenses, additional competition in the markets that we compete in, 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 due to substantial uncertainty but may materially affect our business, financial condition, and results of operations. We assess the impact of COVID-19 in several possible scenarios and concluded that there are no uncertainties that may cast significant doubt on our ability to continue as a going concern or affect significantly on our liquidity.

Key Components of Our Results of Operations

Business Combination

In November 2021, we acquired a portfolio of the following four FDA approved plasma-derived hyperimmune commercial products from Saol: CYTOGAM, HEPAGAM B, VARIZIG and WINRHO SDF. For the period commencing on November 22, 2021 and ending on December 31, 2021, the acquired portfolio contributed $5.4 million and $3.6 million in revenues and gross profit, respectively. If the acquisition had occurred on January 1, 2021, management estimates that portfolio contribution would have been $41.9 million in revenues and $ 6.8 million to the net income.

Under the terms of the agreement, we paid Saol a $95 million upfront payment, and agreed to pay up to an additional $50 million of contingent consideration subject the achievement of sales thresholds for the period commencing on the acquisition date and ending on December 31, 2034. We may be entitled for up to $3 million credit deductible from the contingent consideration payments due for the years 2023 through 2027, subject to certain conditions as defined in the agreement between the parties. In addition, we acquired inventory and agreed to pay the consideration to Saol in ten quarterly installments of $1.5 million each or the remaining balance at the final installment. We estimated the fair value of the contingent consideration and the deferred inventory consideration on the acquisition date at $21.7 million and $13.8 million, respectively.

Pursuant to an earlier engagement with Saol, during 2019, we initiated technology transfer activities for transitioning CYTOGAM manufacturing to our manufacturing facility in Beit Kama, Israel. Through November 22, 2021, we received from Saol a total of $3.8 million in consideration with respect to the technology transfer activities performed. As a result of the consummation of the Saol transaction such previous engagement with Saol expired and the received consideration was accounted for as settlement of preexisting relationship.

The following table details the total acquisition consideration:

	USD in thousands
Cash paid at closing	$ 95,000
Contingent consideration liability	21,705
Deferred inventory consideration	13,788
Settlement of preexisting relationship	(3,786)
Total acquisition cost	126,707

The acquisition was categorized as business combination and accounted for by applying the acquisition method, pursuant to which we identified and valued the acquired assets and assumed liabilities. The excess amount of the acquisition cost over the net value of the acquired assets and assumed liabilities is recorded as goodwill.

The following acquired assets, and their respective fair value as of the acquisition date were identified Inventory: $22.8 million, Customer Relations $33.5 million, Intellectual Property $79.1 million and Assumed Contract Manufacturing Agreement $8.5 million.

We assumed certain of Saol's liabilities for the future payment of royalties (some of which are perpetual) and milestone payments to a third parties subject to the achievement of corresponding CYTOGAM related net sales thresholds and milestones. The fair value of such assumed liabilities at the acquisition date was estimated at $47.2 million. Such assumed liabilities include:

- Royalties: 10% of the annual global net sales of CYTOGAM up to $25.0 million and 5% of net sales that are greater than $25.0 million, in perpetuity; 2% of the annual global net sales of CYTOGAM in perpetuity; and 8% of the annual global net sales of CYTOGAM for period of six years following the completion of the technology transfer of the manufacturing of CYTOGAM to us, subject to a maximum aggregate of $5.0 million per year and for total amount of $30.0 million throughout the entire six years period.

- Sales milestones: $1.5 million in the event that the annual net sales of CYTOGAM in the United States market exceeds $18.8 million during the twelve months period ending June 30, 2022; and, $1.5 million in the event that the annual net sales of CYTOGAM in the United States market exceeds $18.4 million during the twelve months period ending June 30, 2023.

- Milestone: $8.5 million upon the receipt of FDA approval for the manufacturing of CYTOGAM at Company's manufacturing facility.

The following table details the fair value of the identified assets and liabilities as of the acquisition date (*for further details refer to Note 5 of the audited consolidated financial statements for the years ended December 31, 2021 included elsewhere in this Annual Report)*:

	Fair value USD in thousands
Inventory	22,849
Customer Relations	33,514
Intellectual Property	79,141
Assumed Contract Manufacturing Agreement	8,519
Assumed liability	(47,213)
Net identifiable assets	96,810
Goodwill arising on acquisition	29,897
Total acquisition cost	126,707

Intangible assets with a finite useful life are amortized on a straight-line basis over its useful life (estimated 6-20 years). Intangible assets and goodwill are reviewed for impairment whenever there is an indication that the asset may be impaired.

Revenues

In our Proprietary Products segment, we generate revenues from the sale of products to strategic partners (i.e., Takeda and Kedrion), wholesalers in the U.S. market, HMOs and local hospitals and distributors in other ROW markets. Revenues from our Proprietary Products segments also include a recognized portion of prior upfront and milestone and royalty payments from strategic partners. Revenues are presented net of any discounts and/or marketing contribution payments extended to our partners and distributors.

We have historically derived a significant portion of our total revenues from sales of GLASSIA to Takeda. However, as a result of the transition of GLASSIA manufacturing to Takeda in 2021, revenues from the sale of GLASSIA to Takeda decreased in 2021. Sales to Takeda accounted for approximately 25%, 49% and 54% of our total revenues in the years ended December 31, 2021, 2020 and 2019, respectively. Revenue from all sales of GLASSIA comprised approximately 34%, 53% and 58% of our total revenues for the years ended December 31, 2021, 2020 and 2019, respectively. Sales of KEDRAB to Kedrion during the years ended December 31, 2021, 2020 and 2019 accounted for approximately 12%, 14%, and 13% of our total revenues, respectively. Sales from CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF for the year ended December 31, 2021, accounted 5% of our total revenues, which represent sales we generated between November 22, 2021, and December 31, 2021.

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 20%, 19% and 14% of our total revenues for the years ended December 31, 2021, 2020 and 2019, respectively.

We derived approximately 48%, 64% and 66% of our total revenues in the years ended December 31, 2021, 2020 and 2019, respectively, from sales in the United States and North America, approximately 35%, 27% and 25% of our total revenues in the years ended December 31, 2021, 2020 and 2019, respectively, from sales in Israel (including both sales for our Proprietary Products segment and the Distribution segment), approximately 5%, 3% and 4% of our total revenues in the years ended December 31, 2021, 2020 and 2019, respectively, from sales in Europe, approximately 3%, 1% and 2% of our total revenues in the years ended December 31, 2021, 2020 and 2019, respectively, from sales in Asia (excluding Israel), and approximately 9%, 5% and 3% of our total revenues in the years ended December 31, 2021, 2020 and 2019, 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 (including plasma), payroll, utilities, laboratory costs and depreciation. In addition, part of the cost of revenues derived from payment on account of manufacturing services provided by third parties. Cost of revenues also includes provisions for the costs associated with manufacturing scraps and inventory write-offs.

Cost of revenues includes depreciation costs recognized pursuant to the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF. Intangible assets which depreciation is accounted for in the costs of revenues include the acquired products intellectual property and an assumed contract manufacturing agreement.

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. We intend to secure long term plasma supply agreements with other suppliers to support manufacturing needs for CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF, and we plan to leverage the recent acquisition of the plasma collection center to become independent in terms of plasma supply needs.

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 in our Proprietary Products segment, which were 36%, 43% and 46% for the years ended December 31, 2021, 2020 and 2019, respectively, are generally higher than in our Distribution segment, which were 11%, 14% and 15% for the years ended December 31, 2021, 2020 and 2019, respectively.

The reduction in gross profitability during the year ended December 31, 2021, in the Propriety Products segment was mainly as a result of changes in product sales mix, specifically the reduction of GLASSIA sales to Takeda, 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. 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, including the FDA.

Selling and marketing expenses includes depreciation costs of intangible assets recognized pursuant to the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF. Intangible assets which depreciation is accounted for in the selling and marketing expenses include customer relations.

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, audit fees, other professional services 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. During 2020, we realized all of our debt securities (corporate and government).

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. During the years ended December 31, 2020 and 2019, we recognized a tax expense for the entire amount of a deferred tax asset that we initially recognized in 2018 for a portion of our carryforward losses on account of earnings that were offset against the carryforward losses. For the year ended December 31, 2021, we did not account for deferred tax assets nor tax expenses related to such.

As of December 31, 2021, we have net operating loss carryforwards for tax purposes of approximately $33 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 been granted an Approved Enterprise status pursuant to 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.

During the year ended December 31, 2021, following the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF and the plasma collection center in Beaumont, TX, we have initiated commercial operation in the U.S. through our subsidiaries Kamada Inc. and Kamada Plasma LLC. The two entities are subject to U.S. federal and certain state income taxes and file a combined tax return. Income tax expenses due in connection which such activities are included as part of taxes on income in our consolidated statement of operations.

Results of Operations

The following table sets forth certain statement of operations data:

	Year Ended December 31,		
	2021	**2020**	**2019**
	(U.S. Dollars in thousands)		
Revenues from Proprietary Products segment	$ 75,521	$ 100,916	$ 97,696
Revenues from Distribution segment	28,121	32,330	29,491
Total revenues	103,642	133,246	127,187
Cost of revenues from Proprietary Products segment	48,194	57,750	52,425
Cost of revenues from Distribution segment	25,120	27,944	25,025
Total cost of revenues	73,314	85,694	77,450
Gross profit	30,328	47,552	49,737
Research and development expenses	11,357	13,609	13,059
Selling and marketing expenses	6,278	4,518	4,370
General and administrative expenses	12,636	10,139	9,194
Other expense	753	49	330
Operating income (loss)	(696)	19,237	22,784
Financial income	295	1,027	1,146
Income (expense) in respect of securities measured at fair value, net	-	102	(5)
Income (expense) in respect of currency exchange differences and derivatives instruments, net	(207)	(1,535)	(651)
Financial expense	(1,277)	(266)	(293)
Income (loss) before taxes on income	(1,885)	18,565	22,981
Taxes on income	345	1,425	730
Net income (loss)	$ (2,230)	$ 17,140	$ 22,251

Year Ended December 31, 2021 Compared to Year Ended December 31, 2020

Segment Results

	2021	2020	Change 2021 vs. 2020 Amount	Change 2021 vs. 2020 Percent
	(U.S. Dollars in thousands)			
Revenues:				
Proprietary Products	$ 75,521	$ 100,916	$ (25,395)	(25.2)%
Distribution	28,121	32,330	(4,209)	(13.0)%
Total	103,642	133,246	(29,604)	(22.2)%
Cost of Revenues:				
Proprietary Products	48,194	57,750	(9,556)	(16.5)%
Distribution	25,120	27,944	(2,824)	(10.1)%
Total	73,314	85,694	(12,380)	(14.4)%
Gross Profit:				
Proprietary Products	$ 27,327	$ 43,166	$ (15,839)	(36.7)%
Distribution	3,001	4,386	(1,385)	(31.6)%
Total	$ 30,328	$ 47,552	$ (17,224)	(36.2)%

Revenues

In the year ended December 31, 2021, we generated $103.6 million of total revenues, as compared to $133.2 million in the year ended December 31, 2020, a decrease of $29.6 million, or approximately 22.2%. This decrease was primarily due to the transition of GLASSIA manufacturing to Takeda which resulted in an overall $38.7 million year over year decrease of GLASSIA sales. In addition, KEDRAB sales to Kedrion for the year ended December 31, 2021, totaled $11.9 million, a $6.4 million decrease compared to the year ended December 31, 2020, which decrease was a result of relatively higher level of inventory of product at Kedrion as of December 31, 2020, which was due to reduced KEDRAB sales by Kedrion during 2020 as a result of the effect of the COVID-19 pandemic. These decreases were partially offset by $5.4 million of revenues generated from sales of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF following their acquisition from November 22, 2021 through December 31, 2021, the recognition of $5.0 million of GLASSIA sales milestone from for Takeda and $3.9 million of revenues generated from sales to the IMOH of our investigational Anti-SARS-CoV-2 IgG product, as well as an increase in revenues of our other Proprietary products.

Cost of Revenues

In the year ended December 31, 2021, we incurred $73.3 million of cost of revenues, as compared to $85.7 million in the year ended December 31, 2020, a decrease of $12.4 million, or approximately 14.4%. The decrease in costs of revenues is mainly attributable to the decrease in sales volume and mix.

Gross profit

Gross profit and gross margins in our Proprietary Products segment for the year ended December 31, 2021 were $27.3 and 36.2%, respectively, as compared to $43.2 and 42.8% for the year ended December 31, 2020, respectively, representing a decrease of $15.9 million and 36.7%, respectively. Such decrease is primarily attributed to the overall decrease in product sales mix, specifically the decrease in sales of GLASSIA to Takeda and KEDRAB to Kedrion (as detailed above), which sales carry relatively higher gross margins, together with an increase in sales of our products in several ex-U.S. markets, which carry relatively lower gross margins.

In the wake of the transition of GLASSIA manufacturing to Takeda, we effected measures to reduce plant overhead costs, including headcount reduction. Nevertheless, the overall reduction in manufacturing plant utilization resulted in relatively higher cost allocation per each manufactured product. As a result, during the year ended December 31, 2021, we incurred higher impairment costs for inventories carried at net realizable value. We account for impairment costs when the net realizable value of the inventory is lower than the cost incurred in bringing the inventory to its present location and condition.

In addition, for the year ended December 31, 2021, we incurred depreciation expenses in the amount of $0.6 million, related to intangible assets recognized pursuant to a business combination, which reduced the gross profits.

Gross profit and gross margins in our Distribution segment for the year ended December 31, 2021 were $3.0 and 10.7%, respectively, as compared to $4.4 and 13.6% for the year ended December 31, 2020, respectively, representing a decrease of $1.4 million and 31.6%, respectively. Such decrease is primarily related to change in product sales mix in this segment, specifically the year over year increased proportion of sales of IVIG of overall sales in this segment. As a tender based product, sales of IVIG carry relatively lower gross margins as compared to other products in this segment.

Research and Development Expenses

In the year ended December 31, 2021, we incurred $11.4 million of research and development expenses, as compared to $13.6 million in the year ended December 31, 2020, a decrease of $2.2 million, or approximately 16.2%. The decrease was primarily due to reduction in costs associated with our pivotal Phase 3 InnovAATe clinical trial of our Inhaled AAT for treatment of AATD. As a result of the continued effect of the COVID-19 pandemic, we incurred delays and challenges in connection with the opening of additional study sites and recruitment of patient participants, which resulted in the reduction of costs. In addition, during the year ended December 31, 2021, we reduced the development of our investigational Anti-SARS-CoV-2 IgG product as a potential treatment for COVID-19. Given the increased vaccination rate of the population as well as approvals of monoclonal antibodies for COVID-19, we are currently evaluating the market potential of this product, and the continuation of its development program.

Research and development expenses accounted for approximately 10.9% and 10.2% of total revenues for the years ended December 31, 2021 and 2020, respectively.

Set forth below are the research and development expenses associated with our major development programs in the years ended December 31, 2021 and 2020:

	Year ended December 31,	
	2021	**2020**
Inhaled AAT	$ 2,562	$ 3,266
Anti-SARS-CoV-2	180	1,110
Recombinant AAT	528	426
Unallocated salary	5,076	6,045
Unallocated facility cost allocated to research and development	2,138	2,064
Unallocated other expenses	873	698
Total research and development expenses	$ 11,357	$ 13,609

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, 2021 and 2020, we incurred $5.1 million and $6.0 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 $0.9 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 — Risks 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, 2021, we incurred $6.3 million of selling and marketing expenses, as compared to $4.5 million in the year ended December 31, 2020, an increase of $1.8 million, or approximately 39%. This increase was primarily due to costs related to the marketing and distribution of newly acquired CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF as well as costs associated with pre-launch activities of new products in the Distribution segment that were launched during the year ended December 31, 2021 or are expected to be launched during the beginning of 2022.

In addition, for the year ended December 31, 2021, we incurred depreciation expenses in the amount of $0.2 million, related to intangible assets recognized pursuant to a business combination, which reduced the gross profits.

Selling and marketing expenses accounted for approximately 6.1% and 3.4% of total revenues for the years ended December 31, 2021 and 2020, respectively.

General and Administrative Expenses

In the year ended December 31, 2020, we incurred $12.6 million of general and administrative expenses, as compared to $10.1 million in the year ended December 31, 2019, an increase of $2.5 million, or approximately 24.6%. This increase was primarily due to costs associated with the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF (including advisory, legal and other professional fees) totaling $1.2 million as well as a $0.9 million increase in directors’ and officer’s liability insurance related costs.

General and administrative expenses accounted for approximately 12.2% and 7.6% of total revenues for the years ended December 31, 2021 and 2020, respectively.

Other expenses

In the years ended December 31, 2021 and 2020, we incurred $0.8 and $0.1 million of other expenses. In connection with the transition of GLASSIA manufacturing to Takeda, during the second and third quarter of 2021, we implemented a planned workforce downsizing and incurred a one-time expense of $0.7 million related to excess severance remuneration for employees who were laid-off as part of this downsizing, which costs were accounted for in other expenses.

Financial Income

In the years ended December 31, 2021 and 2020, we generated $0.3 and $1.0 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. During 2020 we liquidated our securities portfolio and therefore, did not incur income in respect of securities measured at fair value, net, in 2021.

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

In the year ended December 31, 2021, we incurred $0.2 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 $$1.5 million in the year ended December 31, 2020.

Financial Expenses

In the year ended December 31, 2021, we incurred $1.3 million of financial expenses, as compared to $0.3 million in the year ended December 31, 2020. Financial expenses in the year ended December 31, 2021, included interest costs on debt facility obtained to partially fund the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF. See below "Liquidity and Capital Resources."

Taxes on Income

In the year ended December 31, 2021, we recorded a $0.3 million tax expense primarily related to excess costs tax payment due to the Israeli tax authority and current taxes on account of our U.S commercial operations. In the year ended December 31, 2020, we recorded a $1.4 million tax expense relating 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, 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.

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.

Quarterly Results of Operations

The following tables set forth unaudited quarterly consolidated statements of operations data for the four quarters of fiscal years 2021 and 2020. 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, 2021	**September 30, 2021**	**June 30, 2021**	**March 31, 2021**	**December 31, 2020**	**September 30, 2020**	**June 30, 2020**	**March 31, 2020**
	(U.S. Dollars in thousands)							
Revenues from Proprietary Products	$ 18,205	$ 17,123	$ 19,323	$ 20,870	$ 23,283	$ 29,691	$ 22,625	$ 25,317
Revenues from Distribution	13,264	5,911	4,916	4,030	8,259	5,634	10,464	7,973
Total revenues	31,469	23,034	24,239	24,900	31,542	35,325	33,089	33,290
Cost of revenues from Proprietary Products	12,589	12,078	11,059	12,468	13,933	15,936	12,934	14,947
Cost of revenues from Distribution	12,285	5,226	4,108	3,501	7,444	4,568	9,040	6,892
Total cost of revenues	24,874	17,304	15,167	15,969	21,377	20,504	21,974	21,839
Gross profit	6,595	5,730	9,072	8,931	10,165	14,821	11,115	11,451
Research and development expenses	3,448	2,545	2,736	2,628	3,274	3,365	3,623	3,347
Selling and marketing expenses	2,475	1,256	1,424	1,123	1,221	1,179	1,178	940
General and administrative expenses	3,833	2,691	3,303	2,809	3,006	2,514	2,307	2,312
Other expense (income)	141	42	563	7	15	0	32	2
Operating income (loss)	(3,302)	(804)	1,046	2,364	2,649	7,763	3,975	4,850
Financial income	18	68	99	110	162	250	298	317
Financial expenses	(1,099)	(61)	(63)	(53)	(62)	(69)	(58)	(77)
Income (expense) in respect of securities measured at fair value, net	-	-	-	-	-	0	0	102
Income (expense) in respect of currency exchange differences and derivatives instruments, net	(281)	(48)	(145)	266	(839)	(761)	(367)	432
Income (loss) before taxes on income	(4,664)	(845)	937	2,687	5,518	6,037	6,373	5,053
Taxes on income	345	-	-	-	156	214	230	130
Net income (loss)	$ (5,009)	$ (845)	$ 937	$ 2,687	$ 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, 2021, 2020 and 2019, totaled $18.6 million, $109.3 million and $73.9 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 capital expenditures for the years ended December 31, 2021, 2020 and 2019 were $3.7 million, $5.5 million and $2.3 million, respectively. Our capital expenditures currently relate primarily to the maintenance and improvements of our facilities. We expect our capital expenditures to increase in the coming years mainly due to the planned expansion our plasma collection operations as well as to facilitate the transition manufacturing of HEPGAM B, VARIZIG and WINRHO SDF to our manufacturing facility in Beit Kama, Israel, which will require possible upgrades to plant infrastructure as well as to upgrade manufacturing automation. To date, we have not made any material commitments towards such planned expenditures.

In addition to our capital expenditure, during the year ended December 31, 2021, we acquired CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF from Saol. Under the terms of the agreement, we paid Saol a $95 million upfront payment, and agreed to pay up to an additional $50 million of contingent consideration subject the achievement of sales thresholds for the period commencing on the acquisition date and ending on December 31, 2034. We may be entitled for up to $3 million credit deductible from the contingent consideration payments due for the years 2023 through 2027, subject to certain conditions as defined in the agreement between the parties. In addition, we acquired inventory and agreed to pay the consideration to Saol in ten quarterly installments of $1.5 million, each or the remaining balance at the final installment. In addition, we assumed certain of Saol's liabilities for the future payment of royalties (some of which are perpetual) and milestone payments to a third parties subject to the achievement of corresponding CYTOGAM related net sales thresholds and milestones. The fair value of such assumed liabilities at the acquisition date was estimated at $47.2 million. For additional information also see above under "Key Components of Our Results of Operations—*Business Combination* and Note 19e to our consolidated financial statements included in this Annual Report.

We have entered into long term lease agreements with respect to office facility, storage spaces, vehicles and certain office equipment. The terms of such lease arrangements are between 3 to 10 years. The outstanding lease obligation as of December 31, 2021 totaled $4.3 million. For additional information see Note 16 to our consolidated financial statements included in this Annual Report.

We are also obligated to make certain severance or pension payments to our Israeli employees upon their retirement in accordance with Israeli law. For additional information, see "Post-Employment Benefits Liabilities" and Note 2u and Note 18 to our consolidated financial statements included in this Annual Report.

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

Credit Facility and Loan Agreement with Bank Hapoalim B.M.

In connection with the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF from Saol, on November 15, 2021, we secured a $40 million of debt facility from Bank Hapoalim B.M., which is comprised of a $20 million five-year loan and a $20 million short-term revolving credit facility.

The long-term loan bears interest at a rate of SOFR (Secured Overnight Financing Rate) + 2.18% and is repayable in 54 equal monthly installments commencing on June 16, 2022. The credit facility is in effect for a period of 12 months and thereafter, renews automatically for additional terms of 12 months each, unless either party otherwise notifies the other party in writing. Borrowings under the credit facility accrue interest at a rate of SOFR + 1.75 and are repayable no later than 12 months from the date advanced. We are required to pay an annual fee of 2% of the unutilized credit facility.

The terms of the loan and credit facility include certain financial covenants, for the years ending December 31, 2022, and onwards, including that we maintain: (i) minimum equity capital of 30% of the balance sheet and no less than $120 million, examined on a quarterly basis, (ii) a maximum working capital to debt ratio of 0.8, examined on a quarterly basis, and (iii) a minimum debt coverage ratio of 1.1 during 2022-2024 and 1.25 in 2025 and onwards, examined on an annual basis. In addition, the terms of the loan and credit facility contain certain restrictive covenants including, among others, limitations on restructuring, the sale of purchase of assets, material licenses, certain changes of control and the creation of floating charges over our property and assets. In addition, we undertook not to create any first ranking floating charge over all or materially all of our property and assets in favor of any third party unless certain conditions, as defined in the loan agreement, have been satisfied. See "Item 3. Key Information — D. Risk Factors —Risks Related to Our Financial Position and Capital Resources — *Our financial position and operations may be affected as a result of the indebtedness we incurred to partially fund the Saol acquisition*."

Cash Flows from Operating Activities

Net cash used in operating activities was $8.8 million for the year ended December 31, 2021. This net cash used in operating activities reflects net loss of $2.2 million, $7.7 million for non-cash income and expenses, $14.4 million increase in assets, net of liabilities, and $0.1 million of interest income, net of interest and tax expenses paid in cash.

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.

Cash Flows from Investing Activities

Net cash used in investing activities was $61.1 million for the year ended December 31, 2021, which comprises of $96.4 million related to the Saol and B&PR acquisitions, $39.1 million gained from disposition of short-terms investment and $3.7 million of capital expenditures.

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.

Cash Flows from Financing Activities

Net cash provided by financing activities was $18.6 million for the year ended December 31, 2021, and is mainly related to the receipt of the long-term loan from Bank Hapoalim.

Net cash provided by financing activities was $23.3 million for the year ended December 31, 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.

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*".

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.

Business combinations and goodwill:

Upon consummation of an acquisition, and for the purpose of determining the appropriate accounting treatment, the acquirer examines whether the transaction constitutes an acquisition of a business or assets. In determining whether a particular set of activities and assets is a business, we assess whether the set of assets and activities acquired includes, at a minimum, an input and substantive process and whether the acquired set has the ability to produce outputs.

We have an option to apply a 'concentration test' that permits a simplified assessment of whether an acquired set of activities and assets is not a business. The optional concentration test is met if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets.

Transactions in which the acquired is considered a business acquisition are accounted for as a business combination as described below. Conversely, transactions not considered as business acquisition are accounted for as acquisition of assets and liabilities. In such transactions, the cost of acquisition, which includes transaction costs, is allocated proportionately to the acquired identifiable assets and liabilities, based on their proportionate fair value on the acquisition date. In an assets acquisition, no goodwill is recognized, and no deferred taxes are recognized in respect of the temporary differences existing on the acquisition date.

Business combinations are accounted for by applying the acquisition method. The cost of the acquisition is measured at the fair value of the consideration transferred on the acquisition date.

Costs associated with the acquisition that were incurred by the acquirer in the business combination such as: finder's fees, advisory, legal, valuation and other professional or consulting fees, other than those associated with an issue of debt or equity instruments connected to the business combination, are expensed in the period the services are received.

Contingent consideration is recognized at fair value on the acquisition date and classified as a financial asset or liability in accordance with IFRS 9. Subsequent changes in the fair value of the contingent consideration are recognized in profit or loss as finance income or finance expense. If the contingent consideration is classified as an equity instrument, it is measured at fair value on the acquisition date without subsequent remeasurement.

The fair value of an acquiree's previously recognized contingent consideration assumed in connection a business combination is recognized as financial liability on the acquisition date. Subsequently, the financial liability is measured at amortized cost, per IFRS 9. Remeasurement of the financial liability is recognized as finance income or expense in the statement of operations.

Goodwill is initially measured at cost which represents the excess of the acquisition consideration over the net identifiable assets acquired and liabilities assumed.

On March 1, 2021, we acquired the plasma collection center and certain related rights and assets from the privately held B&PR of Beaumont, TX, USA. For more information see Note 5(a) to our consolidated financial statements included in this Annual Report for more details.

On November 22, 2021, we entered into an asset purchase agreement with Saol for the acquisition of a portfolio of four FDA-approved plasma-derived hyperimmune commercial products. See Note 2(d) and Note 5 to our consolidated financial statements included in this Annual Report for additional information.

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. The determination of the standard manufacturing capacity is subject to significant assumptions such as expected demand for our products, expected industry sales growth and manufacturing schedules. Management's determination of deviations from quality standards is based on qualitative assessment, historical data and our past experience.

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 2021.

Goodwill:

We review goodwill for impairment once a year, on December 31, or more frequently if events or changes in circumstances indicate that there is an impairment.

Goodwill is tested for impairment by assessing the recoverable amount of the cash-generating unit (or group of cash-generating units) to which the goodwill has been allocated. An impairment loss is recognized if the recoverable amount of the cash-generating unit (or group of cash-generating units) to which goodwill has been allocated is less than the carrying amount of the cash-generating unit (or group of cash-generating units). Any impairment loss is allocated first to goodwill. Impairment losses recognized for goodwill cannot be reversed in subsequent periods.

As of December 31, 2021, we estimated the recoverable amount of the cash generating unit to which the goodwill has been allocated. The recoverable amount was calculated based on discounted cash flows expected to be generated from such cash generating unit which was based on a five year financial forecast approved by our management and using an 11% discount rate. The estimated recoverable amount of the unit was higher than its carrying amount, and therefore there was no need to provide for impairment. A sensitivity test of the discounted cash flow using a range of different discount rates was performed and did not change the result.

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 18 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.

A sensitivity analyses was performed based on reasonably possible changes of the principal assumptions (discount rate and future salary increases) underlying the defined benefit plan.

In the event that the discount rate increases or decreases one percent, and all other assumptions were held constant, the defined benefit obligation would decrease by $266,000 or increase by $310,000, respectively.

In the event that the expected salary growth increases or decreases by one percent, and all other assumptions were held constant, the defined benefit obligation would increase by $294,000 or decrease by $252,000, respectively.

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, 2021, 2020 and 2019, 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 16 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 March 15, 2022.

Name	Age	Position
Executive Officers:		
Amir London	53	Chief Executive Officer
Chaime Orlev	51	Chief Financial Officer
Eran Nir	49	Chief Operating Officer
Yael Brenner	58	Vice President, Quality
Hanni Neheman	52	Vice President, Marketing & Sales
Yifat Philip	45	Vice President, General Counsel and Corporate Secretary
Orit Pinchuk	56	Vice President, Regulatory Affairs and PVG
Ariella Raban	46	Vice President, Human Resources
Jon Knight	56	Vice President of US Commercial Operations
Directors:		
Lilach Asher Topilsky*	51	Chairman of the Board of Directors
Amiram Boehm *	50	Director
Ishay Davidi*	60	Director
Karnit Goldwasser*	45	Director
Jonathan Hahn	39	Director, Chairman of Strategy Committee
Lilach Payorski*	48	Director, Chairman of Audit Committee
Leon Recanati*	73	Director, Chairman of Compensation Committee
Prof. Ari Shamiss, MD*	63	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 from December 2013. Mr. London brings with him over 25 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.

Eran Nir was appointed as our Chief Operating Officer as March 1, 2022, responsible for operation and research and development activities. Prior to that Mr. Nir 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.

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.

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.

Jon Knight is our Vice President of US Commercial Operations commencing as of March 15, 2022. Mr. Knight joins with nearly 25 years of Life Sciences experiences, primarily focusing on commercializing innovative specialty plasma-products. Prior to joining us, Mr. Knight served in a variety of commercial leadership positions. Most recently Mr. Knight was responsible for Trade Relations at TherapeuticsMD successfully launching three innovative products into the market. Mr. Knight's professional background also includes leadership positions at Prometic Life Sciences, CIS by Deloitte, Cardinal Health, Cangene bioPharma and Nabi bioPharmaceuticals. Mr. Knight received an MBA from Colorado State University and a B.A. in Biology from Colorado Mesa University.

Dr. Michal Ayalon, who served as our Vice President, Research and Development and IP from February 2019, ceased to serve in such capacity on February 28, 2022.

Directors

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), SOS Ltd. 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).

Amiram Boehm has served on our board of directors since December 2019 and serves as a member of our Strategy Committee. Mr. Boehm 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), Hadera Paper Ltd. (TASE), Rekah Pharmaceuticals Ltd. (TASE), TAT Technologies Ltd. (NASDAQ, TASE), PCB Technologies Ltd. (TASE), GreenStream 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), Solbar Industries Ltd. (previously traded on the TASE), Ham-Let (Israel-Canada) Ltd. (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 B.A. degree in Economics, an LL.B degree from Tel Aviv University and a Joint M.B.A. 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), Bet Shemesh Engines Ltd. (TASE), C. Mer Industries Ltd. (TASE), G1 Security Systems Ltd. (TASE), PCB Technologies Ltd. (TASE), Rekah Pharmaceutical Industries (TASE), SOS Ltd., GreenStream 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), Ham-Let 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), Tadir-Gan (Precision Products) 1993 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). Ms. Goldwasser previously served as a director at ELA Recycling Corporation (2015-September 2021), 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, a M.Sc. degree in Civil Engineering, specializing in Hydrodynamics and Water Resources, both from the Technion – Israel Institute of Technology, and a M.A. 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 B.A. degree from San Andrés University and a M.B.A. degree from New York University — Stern School of Business, with specializations in Finance and Entrepreneurship.

Lilach Payorski has served on our board of directors since December 2021, and serves as the Chairman of our Audit Committee. Ms. Payorski served as the Chief Financial Officer of Stratasys Ltd (NASDAQ: SSYS), a developer and manufacturer of 3D printers and additive solutions, from January 2017 to February 2022. Prior to that, from December 2012 until December 2016, Ms. Payorski served as Senior Vice President, Corporate Finance at Stratasys. From December 2009 to December 2012, Ms. Payorski served as Head of Finance at PMC-Sierra (NASDAQ: PMCS), a company operating in the semiconductors industry, which was subsequently acquired by Microsemi Corporation. Prior to that, from March 2005 to December 2009, Ms. Payorski served as Compliance Controller at Check Point Software Technologies Ltd. (NASDAQ: CHKP), a security company. Ms. Payorski also served as corporate controller at Wind River Systems (NASDAQ: WIND), a software company, which was subsequently acquired by Intel Corporation, from June 2003 to March 2005. Earlier in her career, from March 1997 to June 2003, Ms. Payorski worked as a chartered public accountant at Ernst & Young LLP, both in Israel and later in Palo Alto, CA. Ms. Payorski currently serves as the chairman of the audit committee of Scodix Ltd (TASE: SCDX). Ms. Payorski holds a B.A. degree in Accounting and Economics from Tel Aviv University. Ms. Payorski also completed the Board of Directors and Senior Corporate Officers Program at LAHAV, School of Management, Tel Aviv University.

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, 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 M.B.A. 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 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, Prof. Shamiss 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).

David Tsur has served on our board of directors since our inception and serves as a member of our Strategy Committee. Mr. Tsur served as the Active Deputy Chairman on a half-time basis from July 2015 until December 31, 2019. Mr. Tsur served as our Chief Executive Officer from our inception until July 2015. Mr. Tsur currently serves as the Chairman of the Board of Directors of Kanabo Ltd. (LSE) and as a director of BioHarvest Sciences Inc. (CSE). 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 holds a B.A. degree in Economics and International Relations and an M.B.A. 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 Ms. Lilach Payorski, Ms. Karnit Goldwasser and Prof. Ari Shamiss. Ms. Lilach Payorski 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 Lilach Payorski 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, Mrs. Lilach Asher-Topilsky, Ms. Karnit Goldwasser and Ms. Lilach Payorski. 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, 2021, was approximately $3.05 million. This amount includes approximately $0.27 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. We did not grant equity-based compensation to our officers and directors during the year ended December 31, 2021. As of December 31, 2021, options to purchase 2,182,483 of our ordinary shares granted to our officers and directors as a group were outstanding, of which options to purchase 452,009 of our ordinary shares were vested, with a weighted average exercise price of NIS 20.1 per ordinary share. In addition, as of December 31, 2021, 144,081081 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 85,440 (approximately $26,450), as well as a fee of NIS 3,293 (approximately $1,019) for each board or committee meeting attended in person, NIS 1,976 (approximately 612) for each board or committee meeting attended via telephone or videoconference and NIS 1,647 (approximately $510) 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, Chief Financial Officer, Chief Operating Officer, Vice President, Regulatory Affairs and PVG and Vice President, General Counsel and Corporate Secretary, during or with respect to the year ended December 31, 2021. 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*	$ 412	$ 89	$ 141	$ 21	$ 663
Chaime Orlev *Chief Financial Officer*	$ 264	$ 48	$ 11	$ 19	$ 342
Eran Nir *Chief Operating Officer*	$ 256	$ 35	$ 10	$ 31	$ 332
Orit Pinchuk *Vice President, Regulatory Affairs and PVG*	$ 227	$ 24	$ 10	$ 23	$ 284
Yifat Philip *Vice President, General Counsel and Corporate Secretary*	$ 201	$ 24	$ 33	$ 22	$ 280

(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, 2021 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.

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, Chief Operating Officer. 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. Mr. Eran Nir has served our Chief Operating Officer since March 1, 2022. 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.

Orit Pinchuk, *Vice President, Regulatory Affairs and PVG.* Effective as of January 1, 2014, we entered into an employment agreement with Ms. Orit Pinchuk with respect to her employment as our Vice President, Regulatory Affairs and PVG. 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.

Yifat Philip, *Vice President, General Counsel and Corporate Secretary.* Effective as of October 15, 2020, we entered into an employment agreement with Ms. Yifat Philip with respect to her employment as our Vice President, General Counsel and Corporate Secretary. 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.

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 may be 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

During 2021, as result of the transition of GLASSIA manufacturing to Takeda, we implemented a workforce downsizing. As of December 31, 2021, we employed 355 employees, all of whom in Israel, according to the following division:173 in Operations, 90 in Quality, 14 in Research and Development, 17 in Regulation, 2 in Business Development, 5 in Medical & Clinical, 19 in sales, Israel, 13 in Human Resources & Administration, 18 in Finance and 4 in Legal. In our US Commercial Operations and plasma collection center we employed total of 9 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.

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, and eligibility for certain compensation terms and welfare. In November 2018, we signed a further collective bargaining agreement with the employees' committee and the Histadrut, which expired in December 2021, and we are currently in negotiations with the employees' committee on a new collective bargaining agreement. On March 3, 2022, during the course our negotiations with the Histadrut and the employees' committee on the extension of the collective bargaining agreement, the employee's committee elected to declare a labor dispute. Approximately 55% of our employees, all of whom are located at our Beit Kama facility, currently work under the collective bargaining agreement signed in November 2018. 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. In addition, 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 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 44,800,504 ordinary shares outstanding as of March 15, 2022. 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.

	Ordinary Shares Beneficially Owned	
Name	**Number**	**Percentage**
Executive Officers		
Amir London (1)	195,375	*
Chaime Orlev (2)	40,933	*
Eran Nir (3)	39,885	*
Yael Brenner (4)	25,330	*
Hanni Neheman (5)	24,776	*
Yifat Philip (6)	9,375	*
Orit Pinchuk (7)	50,430	*
Ariella Raban (8)	45,014	*
Jon Knight (9)	-	*
Directors		
Lilach Asher Topilsky (10)	13,250	*
Amiram Boehm (11)	13,250	*
Ishay Davidi (12)	9,465,958	21.12%
Karnit Goldwasser (13)	13,250	*
Jonathan Hahn (14)	1,938,956	4.32%
Lilach Payorski (15)	-	-
Leon Recanati (16)	3,613,561	8.06%
Ari Shamiss (17)	3,125	*
David Tsur (18)	720,619	1.6%
Directors and executive officers as a group (16 persons) (19)	16,213,087	36.17%

* Less than 1% of our ordinary shares.

(1) Includes (i) 27,375 ordinary shares (ii) 13,875 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 154,125 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.55 (or $5.95) per share, which expire between March 2, 2023 and September 25, 2026. Does not include unvested options to purchase 61,875 ordinary shares and 20,625 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table. Does also not include options to purchase 400,000 ordinary shares which are subject to shareholder approval at the meeting that is expected to take place during 2022.

(2) Includes (i) 9,764 ordinary shares, (ii) 469 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 30,700 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.08 (or $5.81) per share, which expire between May 12, 2024 and December 20, 2025. Does not include unvested options to purchase 94,200 ordinary shares and 1,402 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) 8,529 ordinary shares, (ii) 4,372 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 26,984 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 20.62 (or $6.28) per share, which expire between May 24, 2023 and December 20, 2025. Does not include unvested options to purchase 94,200 ordinary shares and 111,402 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) 4,398 ordinary shares, (ii) 6,332 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 14,600 ordinary shares exercisable within 60 days of the date of the table, at exercise price of NIS 20.62 (or $6.28) per share, which expire between October 27, 2022 and December 20, 2025. Does not include unvested options to purchase 64,200 ordinary shares and 1,402 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) 2,734 ordinary shares, (ii) 152 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 21,890 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 18.17 (or $5.53) per share, which expire between October 27, 2022 and December 20, 2025. Does not include unvested options to purchase 61,359 ordinary shares and 453 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(6) Subject to options to purchase 9,375 ordinary shares exercisable within 60 days of the date of the table, at an exercise price of NIS 29.41 (or $8.96 per share, which expire on April 15, 2027. Does not include unvested options to purchase 75,625 ordinary shares that are not exercisable within 60 days of the date of the table.

(7) Includes (i) 10,264 ordinary shares, (ii) 466 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 39,700 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 19.41 (or $5.91) per share, which expire between October 27, 2022 and December 20, 2025. Does not include unvested options to purchase 64,200 ordinary shares and 1,402 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) 7,706 ordinary shares, (ii) 545 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 36,763 ordinary shares exercisable within 60 days of the date of the table, at an exercise price of NIS 19 (or $5.79) per share, which expire between October 27, 2022 and December 20, 2025. Does not include unvested options to purchase 64,437 ordinary shares and 1,481 restricted share units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(9) Does not include unvested options to purchase 60,000 ordinary shares 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 13,250 ordinary shares exercisable within 60 days of the date of the table, at an exercise price of NIS 23.67 (or $7.2) per share, which expire on September 25, 2026. Does not include unvested options to purchase 13,250 ordinary shares that are not exercisable or do no vest, as applicable, within 60 days of the date of the table. Does also not include options to purchase 30,000 ordinary shares that are subject to shareholder approval at a meeting that is expected to take place during 2022.

(11) Subject to options to purchase 13,250 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 $7.2) per share, which expire on September 25, 2026. Does not include unvested options to purchase 13,250 ordinary shares that are not exercisable within 60 days of the date of the table. Does also not include options to purchase 30,000 ordinary shares that are subject to shareholder approval at a meeting that is expected to take place during 2022.

(12) 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) to table under “Item 7. Major Shareholders and Related Party Transactions—Major Shareholders”; and (ii) 13,250 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 $7.2) per share, which expire on September 25, 2026. Does not include unvested options to purchase 13,250 ordinary shares held by Mr. Ishay Davidi that are not exercisable within 60 days of the date of the table. Does also not include options to purchase 30,000 ordinary shares that are subject to shareholder approval at a meeting that is expected to take place during 2022.

(13) Subject to options to purchase 13,250 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 $7.2) per share, which expire on September 25, 2026. Does not include unvested options to purchase 13,250 ordinary shares that are not exercisable within 60 days of the date of the table. Does also not include options to purchase 30,000 ordinary shares that are subject to shareholder approval at a meeting that is expected to take place during 2022.

(14) 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. In addition, includes options to purchase 35,438 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 21.44 (or $6.9) per share, which expire between March 2, 2023 and September 25, 2026. Does not include unvested options to purchase 16,062 ordinary shares held by Mr. Jonathan Hahn that are not exercisable within 60 days of the date of the table. Does also not include options to purchase 30,000 ordinary shares that are subject to shareholder approval at a meeting that is expected to take place during 2022.

(15) Does not include options to purchase 30,000 ordinary shares that are subject to shareholder approval at a meeting that is expected to take place during 2022.

(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, a director, who exercises sole voting and investment power over the shares held by Gov. In addition, includes options to purchase 40,438 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 20.66 (or $6.29) per share, which expire between March 2, 2023 and September 25, 2026. Does not include unvested options to purchase 16,062 ordinary shares that are not exercisable within 60 days of the date of the table. Does also not include options to purchase 30,000 ordinary shares that are subject to shareholder approval at a meeting that is expected to take place during 2022.

(17) Subject to options to purchase 3,125 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 29.68 (or $9.04) per share, which expire on June 10, 2027. Does not include unvested options to purchase 6,875 ordinary shares that are not exercisable within 60 days of the date of the table. Does also not include options to purchase 30,000 ordinary shares that are subject to shareholder approval at a meeting that is expected to take place during 2022.

(18) Mr. David Tsur directly holds 680,181 ordinary shares. In addition, includes options to purchase 40,438 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 20.66 (or $6.64) per share, which expire between March 2, 2023 and September 25, 2026. Does not include unvested options to purchase 16,602 ordinary shares that are not exercisable within 60 days of the date of the table. Does also not include options to purchase 30,000 ordinary shares that are subject to shareholder approval at a meeting that is expected to take place during 2022.

(19) See footnotes (1)-(18) 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"). The 2011 Plan expired in July 2021 and in August 2021, we extended the 2011 Plan by an additional ten years, until August 9, 2031, and adopted a few additional amendments to the 2011 Plan. References below to the "2011 Plan" refer to the 2011 Plan as amended in August 2021. 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 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.

In February 2022, the Board of Directors adopted the U.S. Taxpayer Appendix to the 2011 Plan (the "US Appendix"), which provides for the grant of options and restricted shares to persons who are subject to U.S. federal income tax. The Appendix provides for the grant to U.S. employees of options that qualify as incentive stock options ("ISOs") under the U.S. Internal Revenue Code of 1986, as amended. The aggregate maximum number of ordinary shares that may be issued upon the exercise of ISOs granted under the 2011 Plan is 500,000. The grant of ISO's is subject to the approval of the Appendix by our shareholders within 12 months of its approval by our Board of Directors.

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 upon termination of such 90-day period there is an ongoing 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 limited 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, the board or compensation committee may take one of the following actions: (i) provide that awards then outstanding under the 2011 Plan shall be assumed or substituted for shares or other securities of the surviving or acquiring entity, under such terms and conditions determined by the board or the compensation committee; (ii) provide for the acceleration of vesting of all a part of any awards then outstanding under the 2011 Plan, under such terms and conditions as the Board or the compensation committee shall determine; or (iii) provide for the cancellation of any award without any consideration, if the fair market value per share on the date of the transaction does not exceed the purchase price of any such award or if such award would not otherwise be exercisable or vested, even in the event that the fair market value per share on the date of the transaction, exceeds the purchase price of any such award. 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, 2021, an aggregate of 1,396,002 ordinary shares were reserved for future issuance under the 2011 Plan (subject to certain adjustments specified in the 2011 Plan), and options to purchase 1,504,678 ordinary shares were outstanding under the 2011 Plan, of which options to purchase 1,067,363 ordinary shares were vested as of such date, and 49,561 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. On February 28, 2022, the Board of Directors approved an increase of 1,400,000 ordinary shares reserved for future issuance under the 2011 Plan. See Note 28 to our consolidated financial statements included in this Annual Report for information regarding awards to directors, executive officers and employees subsequent to December 31, 2021.

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 44,800,504 ordinary shares outstanding as of March 15, 2022. 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	21.10%
Leon Recanati(2)	3,613,561	8.06%
The Phoenix Holdings Ltd.(3)	3,634,342.	8.11%

(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 13,250 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) to the table under "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, who exercises sole voting and investment power over the shares held by Gov. In addition, includes options to purchase 40,438 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 20.66 (or $6.29) per share, which expire between March 2, 2023 and September 25, 2026. Does not include unvested options to purchase 16,062 ordinary shares that are not exercisable within 60 days of the date of the table.

(3) Based solely upon, and qualified in its entirety with reference to the table in Item 4 to Schedule 13G filed with the SEC on February 7, 2022. According to the Statement, the shares are beneficially owned by various direct or indirect, majority or wholly-owned subsidiaries of the Phoenix Holding Ltd. (the "Subsidiaries"), which manage their own funds and/or the funds of others (including for holders of exchange-traded notes or various insurance policies, members of pension or provident funds, unit holders of mutual funds, and portfolio management clients). Each of the Phoenix Holding Ltd. and Subsidiaries disclaims any beneficial ownership of the reported shares in excess of their actual pecuniary interest therein.

To our knowledge, based on information provided to us by our transfer agent in the United States, as of March 11, 2022, we had two shareholders of record registered with an address in the United States, holding approximately 22.887% 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 22.886% of our ordinary shares were held of record by one U.S. nominee company, CEDE & Co.

To our knowledge, other than as disclosed in the table above, our other filings with the SEC and this Annual Report, there has been no significant change in the percentage ownership held by any major shareholder since January 1, 2019.

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 originally entered into prior to the FIMI Funds becoming a shareholder of our company and on an arm's length basis, one of which was subsequently superseded by a new agreement entered into between the parties. 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.

Tax benefits under the 2021 Amendment that became effective on August 15, 2021

Israel's 2021-2022 Budget Law published on November 15, 2021 (the "2021 Amendment"), introduced a new dividend distribution ordering rule according to which in the event of a dividend distribution, earnings that were tax exempt under the historical Approved or Beneficial Enterprise regimes, referred to as "trapped earnings," must be distributed on a pro-rata basis from any dividend distribution, commencing August 15, 2021 and onwards.

The 2021 Amendment also includes a temporary order, in force for one year from its enactment on November 15, 2021, to enhance the release of such trapped earnings under the historical Approved and Beneficial Enterprise regimes, that are generally subject to a claw-back of the corporate tax rate that was not paid on such earnings upon their distribution, according to which Israeli companies that have trapped earnings will be able to distribute such earnings with up to a 60% "discount" of the applicable corporate tax rate, but not less than a 6% corporate tax rate. The applicable corporate tax rate is determined based on a formula that considers the ratio of the "released" earnings out of the trapped earnings and the historical corporate tax rate the company was exempt from, and allows the maximum benefit if the entire amount of trapped earnings is to be released.

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 $2.2 million as of December 31, 2021, 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 $1.1million (excluding any interest thereon) as of December 31, 2021.

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 (currently, 23%).

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.

Under a temporary order issued under Israel's 2021-2022 Budget Law in force for a period of one year from November 15, 2021, Israeli companies that have trapped earnings under the historical Approved and Beneficial Enterprise regimes, that are generally subject to a claw-back of the corporate tax rate that was not paid on such earnings upon their distribution, will be able to distribute such earnings with up to a 60% "discount" of the applicable corporate tax rate, but not less than a 6% corporate tax rate. The applicable corporate tax rate is determined based on a formula that considers the ratio of the "released" earnings out of the trapped earnings and the historical corporate tax rate the company was exempt from, and allows the maximum benefit if the entire amount of trapped earnings is to be released.

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 651,600 in 2020, NIS 647,640 in 2021 and NIS 663,240 in 2022.

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, 2021. 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. Our SEC filings are also generally available to the public via the Israel Securities Authority's Magna website at www.magna.isa.gov.il, and the TASE website at http://www.maya.tase.co.il.

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 floating interest and 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, 2021, 2020 and 2019, 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, 2021, we had open transactions in derivatives in the amount of approximately $19.7 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, 2019	(7.8)
Year ended December 31, 2020	(7.0)
Year ended December 31, 2021	(3.3)

As of December 31, 2021, we had excess assets over liabilities denominated in NIS in the amount of $0.6 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 depreciates against the NIS, we recognize financial income.

As of December 31, 2021, we had foreign currency exposures to currencies other than U.S. dollars (mainly in EUR) amounting to $9 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 $0.06, $0.4 million and $0.05 million as of December 31, 2021, 2020 and 2019, 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, 2021, we have used all of the net proceeds of our initial public offering. Most recently we used the remaining portion of our net proceeds for the acquisition of the four FDA-approved plasma-derived hyperimmune commercial products in November 2021. 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, 2021, 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, 2021 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, 2021. 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 Lilach Payorski 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, 2021 and 2020, 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,	
	2021	**2020**
Audit Fees (1)	$ 291,250	$ 220,000
Tax Fees (2)	187,048	27,453
All Other Fees (3)	65,000	-
Total	$ 543,298	$ 247,453

(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 2021 and 2020 were for compliance with tax regulation. In addition, tax fees in 2021 include fees for services rendered by our auditors in connection with our recent business combination.

(3) Other fees in 2021 is a service rendered by our auditors in connection with our recent business combination

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, 2021, 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"). As permitted under the Companies Law, we do not have a formal charter addressing the nominations process.

- *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 follow certain home country corporate governance practices instead of otherwise applicable 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 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.

Item 16I. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

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-82, 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.
4.26	Kamada Ltd. 2011 Israeli Share Award Plan Appendix – U.S. Taxpayer.
4.27†	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).
4.28†	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).
4.29†	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).
4.30†	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).
4.31†	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).
4.32	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).
4.33†	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).
4.34†	Distribution Agreement, dated as of May 20, 2020, by and between Kamada Ltd. and TUTEUR S.A.C.I.F.I.A. (incorporated by reference to Exhibit 4.33 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 24, 2021)
4.35†	Binding Term Sheet, dated as of April 27, 2020, between Kamada Ltd. and Kedrion S.p.A. (incorporated by reference to Exhibit 4.34 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 24, 2021)
4.36	Asset Purchase Agreement, dated January 31, 2021, by and among Kamada Plasma, LLC and Blood and Plasma Research, Inc (incorporated by reference to Exhibit 4.35 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 24, 2021)
4.37	Asset Purchase Agreement dated November 22, 2021, by and among Saol International Limited, Saol Bermuda Limited, Saol Therapeutics Research Limited, Saol Therapeutics Inc., Saol US Inc., Kamada Limited and Kamada Inc. (incorporated by reference to Exhibit 99.2 to Form 6-K filed with the Securities and Exchange Commission on November 22, 2021).
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.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

† 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: March 15, 2022

Kamada Ltd.

Consolidated Financial Statements as of December 31, 2021

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Kost Forer Gabbay & Kasierer
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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, 2021 and 2020 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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 March 15, 2022 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, 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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were 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 matters 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 matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

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Valuation of Inventory

Description of the Matter

As of December 31, 2021, the Company's inventory totaled $67 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.

Valuation of assets acquired, contingent consideration and assumed liabilities in the asset purchase agreement of Saol Therapeutics.

Description of the Matter

As described in Note 5b to the consolidated financial statements, during November 2021, the Company completed its asset purchase agreement with Saol Therapeutics to acquire a portfolio of four FDA-approved plasma-derived hyperimmune commercial products in a total consideration of $126.7 million. The transaction was accounted for as a business combination. The Company recognized four Intellectual properties, which are the FDA-approved plasma products, customer relations, and production contract (collectively, "the Intangible Assets") in the amounts of $79 million, $33 million, and $8.5 million, respectively. The Intangible Assets acquired were recorded at their estimated fair values as of the date of the acquisition. Furthermore, as part of the valuation of the consideration, the Company will pay to Saol milestone payments, conditioned on the achievement of the products reaching specific thresholds (the "Contingent Consideration"). The Contingent Consideration was recorded at its estimated fair value. Moreover, the Company recognized assumed liabilities in the amount of $47 million, which consist of contingent obligations to pay royalties and millstone payments to third parties (the "Assumed Liabilities"). The Assumed Liabilities were recorded at their estimated fair value.

Auditing the Company's accounting for its asset purchase agreement was complex due to the significant estimation required by management to determine the fair value of the Intangible Assets, the Contingent Consideration, and the Assumed Liabilities. The significant estimation was primarily due to the complexity of the valuation models used by management to measure the fair value of the Intangible Assets, the Contingent Consideration and the Assumed Liabilities, and the sensitivity of the respective fair values to the significant underlying assumptions. The Company used a discounted cash flow method of the income approach to measure the Intangible Assets. The significant assumptions used to estimate the value of the Intangible Assets included discount rates and certain assumptions that form the basis of the forecasted results (e.g. projected revenue growth rates, and profit margins). The Company used a Monte Carlo simulation to measure the Contingent Consideration. The significant assumptions used in the simulation included volatility, discount rate, revenue projections and timing of expected payments. These significant assumptions are forward looking and could be affected by future economic and market conditions. The Company used a Monte Carlo simulation and a discounted cash flow method of the income approach to measure the fair value of the Assumed Liabilities. The significant assumptions used to estimate the value of the Assumed Liabilities included discount rates and certain assumptions that form the basis of the forecasted results (e.g. projected revenue growth rates, and profit margins). The significant assumptions used in the Monte Carlo simulation included volatility, discount rate, revenue projections, and timing of expected payments. These significant assumptions are forward-looking and could be affected by future economic and market conditions.

How We Addressed the Matter in Our Audit

We tested the Company's controls over its accounting for acquisitions. For example, we tested controls over the recognition and measurement of consideration transferred (including Contingent Consideration), Intangible Assets, and the Assumed Liabilities, including the valuation models.

To test the estimated fair value of the Intangible Assets, we performed audit procedures that included, among others, evaluating the Company's use of valuation methodologies and testing the significant assumptions used in the models, including the completeness and accuracy of the underlying data. For example, we compared the significant assumptions used by the Company to current industry, market and economic trends, to the assumptions used to value similar assets in other acquisitions, to the historical results of the acquired business and to other guidelines used by companies within the same industry. We involved our valuation specialists to assist in our evaluation of the significant assumptions and to assist with reconciling the prospective financial information with other prospective financial information prepared by the Company.

To test the fair value of the Contingent Consideration and the Assumed Liabilities, we performed audit procedures that included, among others, assessing the terms of the arrangement, including the conditions that must be met for the Contingent Consideration and the Assumed Liabilities to become payable. We also involved our valuation specialists to assist in evaluating the Company's use of a Monte Carlo simulation and testing the significant assumptions used in the model, including the completeness and accuracy of the underlying data. For example, we compared the significant assumptions used by the Company to current industry, market, economic trends, and to the Company's budgets and forecasts.

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

We have served as the Company's auditor since 2005.
Tel-Aviv, Israel
March 15, 2022

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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, 2021, 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, 2021, 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, 2021 and 2020, the related consolidated statements of profit or loss and other comprehensive income, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated March 15, 2022 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
March 15, 2022

Consolidated Statements of Financial Position

	Note	As of December 31, 2021	2020
		U.S. Dollars in thousands	
Assets			
Current Assets			
Cash and cash equivalents	6	$ 18,587	$ 70,197
Short-term investments	7	-	39,069
Trade receivables, net	8	35,162	22,108
Other accounts receivables	9	8,872	4,524
Inventories	10	67,423	42,016
Total Current Assets		130,044	177,914
Non-Current Assets			
Property, plant and equipment, net	11	26,307	25,679
Right-of-use assets	16	3,092	3,440
Intangible assets, Goodwill and other long-term assets	12	153,663	1,573
Contract asset	19e	5,561	2,059
Total Non-Current Assets		188,623	32,751
Total Assets		$ 318,667	$ 210,665
Liabilities			
Current Liabilities			
Current maturities of bank loans	15a	$ 2,631	$ 238
Current maturities of lease liabilities	16	1,154	1,072
Current maturities of other long term liabilities	15b	17,986	-
Trade payables	13	25,104	16,110
Other accounts payables	14	7,142	7,547
Deferred revenues	19	40	-
Total Current Liabilities		54,057	24,967
Non-Current Liabilities			
Bank loans	15a	17,407	36
Lease liabilities	16	3,160	3,593
Contingent consideration	15b	21,995	-
Other long-term liabilities	15b	43,929	-
Deferred revenues	19e	15	2,025
Employee benefit liabilities, net	18	1,280	1,406
Total Non-Current Liabilities		87,786	7,060
Shareholder's Equity	21		
Ordinary shares		11,725	11,706
Additional paid in capital net		210,204	209,760
Capital reserve due to translation to presentation currency		(3,490)	(3,490)
Capital reserve from hedges		54	357
Capital reserve from share-based payments		4,643	4,558
Capital reserve from employee benefits		(149)	(320)
Accumulated deficit		(46,163)	(43,933)
Total Shareholder's Equity		176,824	178,638
Total Liabilities and Shareholder's Equity		$ 318,667	$ 210,665

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, 2021	2020	2019
		U.S. Dollars in thousands, except for share and per share data		
Revenues from proprietary products	1a	$ 75,521	$ 100,916	$ 97,696
Revenues from distribution		28,121	32,330	29,491
Total revenues	24a,b	103,642	133,246	127,187
Cost of revenues from proprietary products		48,194	57,750	52,425
Cost of revenues from distribution		25,120	27,944	25,025
Total cost of revenues	24c	73,314	85,694	77,450
Gross profit		30,328	47,552	49,737
Research and development expenses	24d	11,357	13,609	13,059
Selling and marketing expenses	24e	6,278	4,518	4,370
General and administrative expenses	24f	12,636	10,139	9,194
Other expense		753	49	330
Operating income		(696)	19,237	22,784
Financial income	24g	295	1,027	1,146
Income (expenses) in respect of securities measured at fair value, net	24g	-	102	(5)
Income (expenses) in respect of currency exchange differences and derivatives instruments, net	24g	(207)	(1,535)	(651)
Financial expense	24g	(1,277)	(266)	(293)
Income before tax on income		(1,885)	18,565	22,981
Taxes on income	23	345	1,425	730
Net Income (Loss)		$ (2,230)	17,140	$ 22,251
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
Gain (loss) on cash flow hedges		-	876	92
Net amounts transferred to the statement of profit or loss for cash flow hedges		(303)	(528)	(23)
Items that will not be reclassified to profit or loss in subsequent periods:				
Remeasurement gain (loss) from defined benefit plan		171	64	(388)
Tax effect		-	19	(11)
Total comprehensive income (loss)		$ (2,362)	$ 17,383	$ 22,064
Earnings per share attributable to equity holders of the Company:	25			
Basic net earnings (loss) per share		$ (0.05)	$ 0.39	$ 0.55
Diluted net earnings per (loss) share		$ (0.05)	$ 0.38	$ 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, 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
Net income								(2,230)	(2,230)
Other comprehensive income (loss)					(303)		171		(132)
Total comprehensive income (loss)			-	-	(303)		171	(2,230)	(2,362)
Exercise and forfeiture of share-based payment into shares	19	444		-	-	(444)			19
Cost of share-based payment						529			529
Balance as of December 31, 2021	$ 11,725	210,204	$ -	$ (3,490)	54	4,643	$ (149)	$ (46,163)	$ 176,824

The accompanying notes are an integral part of the Consolidated Financial Statements.

Consolidated Statements of Cash Flows

	Note	For the year ended December 31, 2021	2020	2019
		U.S. Dollars in thousands		
Cash Flows from Operating Activities				
Net (loss) income		(2,230)	$ 17,140	$ 22,251
Adjustments to reconcile net income to net cash (used in) provided by operating activities:				
Adjustments to the profit or loss items:				
Depreciation and amortization	10,12	5,609	4,897	4,519
Financial expense (income), net		1,189	672	(197)
Cost of share-based payment	21	529	977	1,163
Taxes on income	23	345	1,425	730
(Gain) loss from sale of property and equipment		-	(7)	(2)
Change in employee benefit liabilities, net		45	201	94
		7,717	8,165	6,307
Changes in asset and liability items:				
Decrease(increase) in trade receivables, net		(12,861)	1,332	5,117
Decrease (increase) in other accounts receivables		(1,634)	115	(214)
Decrease (increase) in inventories		(2,373)	1,157	(13,857)
Decrease (increase) in deferred expenses		(6,883)	(3,085)	399
Increase (decrease) in trade payables		7,917	(9,560)	6,259
Increase (decrease) in other accounts payables		(392)	1,736	863
Increase (decrease) in deferred revenues		1,815	1,204	(283)
		(14,411)	(7,101)	(1,716)
Cash paid during the year for:				
Interest paid		(228)	(209)	(243)
Interest received		375	1,211	1,106
Taxes paid		(42)	(101)	(134)
		105	901	729
Net cash (used in) provided by operating activities		$ (8,819)	$ 19,105	$ 27,571

The accompanying notes are an integral part of the Consolidated Financial Statements.

Consolidated Statements of Cash Flows

	Note	For the year ended December 31, 2021	2020	2019
		U.S. Dollars in thousands		
Cash Flows from Investing Activities				
Investment in short term investments, net		$ 39,083	$ (7,646)	$ 1,727
Purchase of property and equipment and intangible assets	10	(3,730)	(5,488)	(2,300)
Business combination		(96,403)		
Proceeds from sale of property and equipment		-	7	9
Net cash used in investing activities		(61,050)	(13,127)	(564)
Cash Flows from Financing Activities				
Proceeds from exercise of share base payments		19	64	16
Receipt of long-term loans		20,000		
Proceeds from issuance of ordinary shares, net		-	24,895	-
Repayment of lease liabilities		(1,221)	(1,103)	(1,070)
Repayment of long-term loans		(205)	(492)	(476)
Net cash provided by (used in) financing activities		18,593	23,364	(1,530)
Exchange differences on balances of cash and cash equivalent		(334)	(1,807)	(908)
Increase (decrease) in cash and cash equivalents		(51,610)	27,535	24,569
Cash and cash equivalents at the beginning of the year		70,197	42,662	18,093
Cash and cash equivalents at the end of the year		$ 18,587	$ 70,197	$ 42,662
Significant non-cash transactions				
Right-of-use asset recognized with corresponding lease liability	16	845	539	5,035
Purchase of property and equipment		$ 1,001	$ 722	$ 992

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 vertically integrated global biopharmaceutical company, focused on specialty plasma-derived therapeutics, with a diverse portfolio of marketed products, a robust development pipeline and industry-leading manufacturing capabilities. The Company's strategy is focused on driving profitable growth from our current commercial activities as well as our manufacturing and development expertise in the plasma-derived biopharmaceutical market. The Company's commercial products portfolio includes its developed and FDA approved products GLASSIA® and KEDRRAB® as well as its recently acquired FDA approved plasma-derived hyperimmune products CYTOGAM®, HEPAGAM B®, VARIZIG® and WINRHO®SDF. The Company has additional four plasma-derived products which are registered in markets outside the U.S. The Company distributes its commercial products portfolio directly, and through strategic partners or third party distributors in more than 30 countries, including the U.S., Canada, Israel, Russia, Brazil, Argentina, India and other countries in Latin America and Asia. The Company has a diverse portfolio of development pipeline products including an inhaled AAT for the treatment of AAT deficiency for which the Company is currently conducting the InnovAATe clinical trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial. The Company leverages its expertise and presence in the Israeli pharmaceutical market to distribute in Israel more than 20 products that are manufactured by third parties and have recently added eleven biosimilar products to its Israeli distribution portfolio, which, subject to EMA and the Israeli MOH approvals, are expected to be launched in Israel between the years 2022 and 2028.

In November 2021, the Company acquired a portfolio of four FDA approved plasma-derived hyperimmune commercial products from Saol Therapeutics ("Saol"). The acquisition of this portfolio furthers the Company's core objective to become a fully integrated specialty plasma company with strong commercial capabilities in the U.S. market, as well as to expand to new markets, mainly in the Middle East/North Africa region, and to broaden the Company's portfolio offering in existing markets. The Company's wholly owned U.S. subsidiary, Kamada Inc., will be responsible for the commercialization of the four products in the U.S. market, including direct sales to wholesalers and local distributers. Refer to Note 5 for further details on this acquisition.

The Company markets GLASSIA in the U.S. through a strategic partnership with Takeda Pharmaceuticals Company Limited ("Takeda"). Pursuant to an agreement with Takeda, the Company terminated the production and sale of GLASSIA to Takeda during 2021 resulting in a significant reduction in revenues. Takeda initiated its own production of GLASSIA for the U.S. market. Commencing 2022, Takeda will pay royalties to the Company at a rate of 12% on GLASSIA's net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually. Refer to Note 19 for further details on the engagement with Takeda.

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), KI Biopharma LLC and Kamada Ireland limited. 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.

NOTE 1: - GENERAL (CONT.)

The Company is complying with the State of Israel mandates and recommendations with respect to its work-force management and 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.

COVID-19 related disruption had various effect on the Company's business activities, commercial operation, revenues and operational expenses however, as a result of the actions taken by the Company, its overall results of operations for the year ended December 31, 2021 were not materially affected. While there is an evident trend of recovery from the pandemic due to the increased vaccination rate of the population, a number of factors including, but not limited to, continued demand for the Company's commercial products, availability of raw materials, 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 the Company's business, financial condition, and results of operations. The Company assess the impact of the COVID-19 in several 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. Material events in the reporting period

Business combination:

On March 1, 2021, the Company acquired the plasma collection center and certain related rights and assets from the privately held B&PR of Beaumont, TX, USA. For more information see Note 5 (a).

On November 22, 2021, the Company entered into an Assets Purchase Agreement (the "Saol APA") with Saol for the acquisition of a portfolio of four FDA-approved plasma-derived hyperimmune commercial products. For more information see Note 5 (b).

e. 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. Business combinations and goodwill:

Upon consummation of an acquisition, and for the purpose of determining the appropriate accounting treatment, the acquirer examines whether the transaction constitutes an acquisition of a business or assets. In determining whether a particular set of activities and assets is a business, the Company assesses whether the set of assets and activities acquired includes, at a minimum, an input and substantive process and whether the acquired set has the ability to produce outputs.

The Company has an option to apply a 'concentration test' that permits a simplified assessment of whether an acquired set of activities and assets is not a business. The optional concentration test is met if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets.

Transactions in which the acquired is considered a business are accounted for as a business combination as described below. Conversely, transactions not considered as business acquisition are accounted for as acquisition of assets and liabilities. In such transactions, the cost of acquisition, which includes transaction costs, is allocated proportionately to the acquired identifiable assets and liabilities, based on their proportionate fair value on the acquisition date. In an assets acquisition, no goodwill is recognized, and no deferred taxes are recognized in respect of the temporary differences existing on the acquisition date.

Business combinations are accounted for by applying the acquisition method. The cost of the acquisition is measured at the fair value of the consideration transferred on the acquisition date.

Costs associated with the acquisition that were incurred by the acquirer in the business combination such as: finder's fees, advisory, legal, valuation and other professional or consulting fees, other than those associated with an issue of debt or equity instruments connected to the business combination, are expensed in the period the services are received.

Contingent consideration is recognized at fair value on the acquisition date and classified as a financial asset or liability in accordance with IFRS 9. Subsequent changes in the fair value of the contingent consideration are recognized in profit or loss as finance income or finance expense. If the contingent consideration is classified as an equity instrument, it is measured at fair value on the acquisition date without subsequent remeasurement.

The fair value of an acquiree's previously recognized contingent consideration assumed in connection a business combination is recognized as financial liability on the acquisition date. Subsequently, the financial liability is measured at amortized cost, per IFRS 9. Remeasurement of the financial liability is recognized as finance income or expense in the statement of operations.

Goodwill is initially measured at cost which represents the excess of the acquisition consideration over the net identifiable assets acquired and liabilities assumed.

e. 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.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

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.

f. 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.

g. 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.

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

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.

   In cases where the difference between the time of receiving payment and the time of transferring the goods or services to the customer is one year or less, the Company applies the practical expedient included in the standard and does not separate a significant financing component.

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, 2021, 2020 and 2019 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.

The Company determines the transaction price separately for each contract with a customer taking into consideration, variable prices, discounts, chargeback, rebates etc , 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.

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, 2021 and 2020, 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 Lease Standard").

The Company chose to apply the provisions of the Lease 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 Lease 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 16.

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.

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

Separately acquired intangible assets are measured on initial recognition at cost including directly attributable costs. Intangible assets acquired in a business combination are measured at fair value at the acquisition date. Expenditures relating to internally generated intangible assets, excluding capitalized development costs, are recognized in profit or loss when incurred.

Intangible assets with a finite useful life are amortized on a straight-line basis over its useful life and reviewed for impairment whenever there is an indication that the asset may be impaired. The amortization period and the amortization method for an intangible asset are reviewed at least at each year end.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Intangible assets with indefinite useful lives are not systematically amortized and are tested for impairment annually or whenever there is an indication that the intangible asset may be impaired. The useful life of these assets is reviewed annually to determine whether their indefinite life assessment continues to be supportable. If the events and circumstances do not continue to support the assessment, the change in the useful life assessment from indefinite to finite is accounted for prospectively as a change in accounting estimate and on that date the asset is tested for impairment. Commencing from that date, the asset is amortized systematically over its useful life.

	Estimated life	Amortization method
Intellectual property	15-20	Straight-line
Customer Relations	20	Straight-line
Production agreement	6	Straight-line
Distribution right	10-15	Straight-line over the contract period
Goodwill	Indefinite	Not amortized

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, 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, 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.

Goodwill:

The Company reviews goodwill for impairment once a year, on December 31, or more frequently if events or changes in circumstances indicate that there is an impairment.

Goodwill is tested for impairment by assessing the recoverable amount of the cash-generating unit (or group of cash-generating units) to which the goodwill has been allocated. An impairment loss is recognized if the recoverable amount of the cash-generating unit (or group of cash-generating units) to which goodwill has been allocated is less than the carrying amount of the cash-generating unit (or group of cash-generating units). Any impairment loss is allocated first to goodwill. Impairment losses recognized for goodwill cannot be reversed in subsequent periods.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

q. Financial instruments

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, 2021 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 19a.

- 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.

NOTE 3: - SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS (CONT.)

- 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 22.

- 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, 2021 no impairment was recorded as the recoverable amount exceeded the book value.

- 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.

- Impairment of goodwill

  The Company reviews goodwill for impairment at least once a year. This requires management to make an estimate of the projected future cash flows from the continuing use of the cash-generating unit (or a group of cash-generating units) to which the goodwill is allocated and to choose a suitable discount rate for those cash flows.

- Purchase price allocation

  The Company allocate the purchase price based on the identifiable assets acquired and liabilities assumed at the acquisition date. The assets and the liabilities assumed are measure the fair value. Significant estimates are required to measure the fair value of the assets and liabilities recognized as a result of the business combination including, future cash flows, discount rate, volatility rate.

- Contingent consideration

  Contingent consideration is presented at fair value. The fair value is determined using valuation techniques and method, using future cash flows discounted. This requires management to make an estimate of the projected future cash flows. For information regarding contingent consideration , please refer to note 5.

NOTE 4: - DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION

a. 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.)

b. 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 believes that the adoption of the Amendment will not have an effect on its financial statements.

c. 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 believes that the adoption of the Amendment will not have an effect on its financial statements.

NOTE 4: - DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (CONT.)

d. Amendment to IFRS 3, Business Combinations

The Amendment replaces the requirement to recognize liabilities from business combinations in accordance with the conceptual framework, the reason being that the interaction between those instructions and the guidance provided in IAS 37 regarding recognition of liabilities was unclear in certain cases.

The Amendment adds an exception to the principle for recognizing liabilities in IFRS 3. According to the exception, contingent liabilities are to be recognized according to the requirements of IAS 37 and IFRIC 21 and not according to the conceptual framework. The Amendment prevents differences in the timing of recognizing liabilities that could have led to the recognition of gains and losses immediately after the business combination (day 2 gain or loss). The Amendment also clarifies that contingent assets are not to be recognized on the date of the business combination.

The amendments are effective for annual reporting periods beginning on or after 1 January 2022 and apply prospectively.

The Company believes that the adoption of the Amendment will not have an effect on its financial statements.

e. Amendment to IAS 12, Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction

The Amendment narrows the scope of the exemption from recognizing deferred taxes as a result of temporary differences created at the initial recognition of assets and/or liabilities, so that it does not apply to transactions that give rise to equal and offsetting temporary differences.

As a result, companies will need to recognize a deferred tax asset or a deferred tax liability for these temporary differences at the initial recognition of transactions that give rise to equal and offsetting temporary differences, such as lease transactions and provisions for decommissioning and restoration.

The Amendment is effective for annual periods beginning on or after January 1, 2023, by amending the opening balance of the retained earnings or adjusting a different component of equity in the period the Amendment was first adopted.

Earlier application is permitted.

The Company believes that the adoption of the Amendment will not have an effect on its financial statements.

NOTE 5: - BUSINESS COMBINATIONS

a. Acquisition of an FDA-Licensed Plasma Collection Center

On March 1, 2021 the Company entered into an Assets Purchase Agreement with the privately-held B&PR of Beaumont, TX, USA, for the acquisition of a plasma collection facility as well as certain related rights and assets . The plasma 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 $1,614 thousand was consummated through Kamada Plasma LLC a , which will operate the Group's plasma collection activity in the U.S.

The Company accounted for the acquisition as a business combination.

The following table details the acquisition consideration:

	USD in thousands
Cash paid	$ 1,404
Payables for acquisition(a)	210
Total acquisition cost	1,614

(a) The acquisition consideration totaled $1,654 thousands, of which an amount of $1,404 thousands was paid at closing, and the balance of $250 thousands will be paid on March 31, 2022. The fair value of such deferred consideration was estimated at $210 as of the date of acquisition.

In connection with the acquisition, the Company incurred cost of $140 thousand which included legal and other consulting fees. These costs were recorded in general and administrative expenses in the statement of profit and loss during 2020 and the first quarter of 2021.

The fair value of the identifiable assets and liabilities on the acquisition date:

	USD in thousands
Inventories	184
Property, plant and equipment	82
Intangible assets (a)	962
	1,228
Other current liability	(30)
Net identifiable assets	1,198
Goodwill arising on acquisition (b)	416
Total acquisition cost	1,614

(a) The Intangible assets represents the FDA License of the plasma collection facility at fair value (Level 3) at the acquisition date, based on Greenfield Method. Under such method, the subject intangible asset is valued using a hypothetical cashflow scenario of developing an operating business in an entity that at inception only holds the subject intangible asset. In measuring the FDA License of the plasma collection facility the Company used an appropriate discount rate of 19%.

NOTE 5: - BUSINESS COMBINATIONS (CONT.)

(b) The goodwill arising as part of the acquisition is attributed to the expected benefits from the synergies of the combination of the Company's activities and those of the acquired plasma collection facility. The goodwill recognized is not expected to be deductible for income tax purposes.

b. Acquisition of a portfolio of four FDA-approved plasma-derived hyperimmune commercial products

On November 22, 2021 (the "Acquisition Date"), the Company entered into the Saol APA for the acquisition of a portfolio of four FDA-approved plasma-derived hyperimmune commercial products. The acquisition of this portfolio furthers our core objective to become a fully integrated specialty plasma company with strong commercial capabilities in the U.S. market, as well as to expand to new markets, mainly in the Middle East/North Africa region, and to broaden our portfolio offering in existing markets. The four acquired products include:

- CYTOGAM (Cytomegalovirus Immune Globulin Intravenous [Human]) (CMV-IGIV) product indicated for the prophylaxis of cytomegalovirus disease associated with the transplantation of the kidney, lung, liver, pancreas, and heart. The product is the sole FDA approved IgG product for this indication.

- WINRHO SDF is a Rho(D) Immune Globulin Intravenous (Human) product indicated for use in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage in the treatment of non-splenectomies, for Rho(D)-positive children with chronic or acute immune thrombocytopenia (ITP), adults with chronic ITP, and children and adults with ITP secondary to HIV infection. WinRho SDF is also used for suppression of Rhesus (Rh) Isoimmunization during pregnancy and other obstetric conditions in non-sensitized, Rho(D)-negative women. The product is FDA approved.

- HEPAGAM B is a hepatitis B Immune Globulin (Human) (HBIg) product indicated to both prevent hepatitis B virus (HBV) recurrence following liver transplantation in hepatitis B surface antigen positive (HBsAg- positive) patients and provide post-exposure prophylaxis. The product is FDA approved.

- VARIZIG [Varicella Zoster Immune Globulin (Human)] is a product that contains antibodies specific for the Varicella zoster virus, and it is indicated for post-exposure prophylaxis of varicella (chickenpox) in high-risk patient groups, including immunocompromised children, newborns, and pregnant women. VARIZIG is intended to reduce the severity of chickenpox infections in these patients. The U.S. Centers for Disease Control (CDC) recommends VARIZIG for postexposure prophylaxis of varicella for persons at high-risk for severe disease who lack evidence of immunity to varicella. The product is the sole FDA approved IgG product for this indication.

The Company accounted for the acquisition as a business combination

For the period commencing on the Acquisition Date and ending on December 31, 2021 the acquired portfolio contributed $5,381 thousand and $251 thousand to the Company's consolidated revenues and Net income, respectively. If the acquisition had occurred on January 1, 2021, management estimates that consolidated revenue would have been $140,000 thousand and consolidated Net Income for the year would have been $4,000 thousand. In determining these amounts, management has assumed that the fair value adjustments, determined as of the acquisition date, that arose on the date of acquisition would have been the same if the acquisition had occurred on January 1, 2021.

NOTE 5: - BUSINESS COMBINATIONS (CONT.)

The following table details the total acquisition consideration:

	USD in thousands
Cash paid at closing	$ 95,000
Contingent consideration liability (a)	21,705
Deferred consideration (b)	13,788
Settlement of preexisting relationship (c)	(3,786)
Total acquisition cost	126,707

(a) Pursuant to the Saol APA, and in addition to the cash paid at closing, the Company agreed to pay up to $50,000 thousand of contingent consideration subject the achievement of sales thresholds for the period commencing on the Acquisition Date and ending on December 31,2034. The Company may be entitled for up to $3,000 thousands credit deductible from the contingent consideration payments due for the years 2023 through 2027, subject to certain conditions as defined in the agreement between the parties. The contingent consideration totaled $21,705 thousands, which represents its fair value (Level 3) at the acquisition date, based on an Option Pricing Method (OPM), "Monte Carlo Simulation" model.

In measuring the contingent consideration liability, the Company used an appropriate risk- adjusted discount rate of 10.6 % and volatility of 13.6 %.

At December 31, 2021 the fair value of the contingent consideration total $21,995 thousand. The increase in the amount of $290 reflects the changes in the value of the liability since the date of acquisition and was recognized as financing expenses in the statement of profit and loss.

In measuring the contingent consideration liability, the Company used an appropriate risk- adjusted discount rate of 10.5 % and volatility of 10.6 %.
Refer to Note 15.

(b) Pursuant to the Saol APA, the Company acquired inventory valued at $14,199 thousand and agreed to pay it in ten quarterly installments of $1,500 thousand, each or the remaining balance at the final installment. Such deferred inventory consideration totaled $13,788 thousand which represents the Fair value (Level 2) at the acquisition date. The interest rate used to calculate such fair value was based on the Company's cost of debt which was estimated based on the long-term bank loan obtained to partially fund the acquisition. Refer to note 15.

(c) In December 2019, the Company entered into a binding term-sheet for a 12-year contract manufacturing agreement with Saol to manufacture CYTOGAM. Through the acquisition date, the Company received a total of $3,786 thousand from Saol to partially fund the technology transfer activities required under such engagement. Such engagement was automatically terminated on the acquisition date, an such funds, previously accounted for as deferred revenues, were offset from the acquisition consideration as settlement of preexisting relationship.

The following tables details the preliminary fair value of the identifiable assets and liabilities on the acquisition date:

	Fair value USD in thousands
Inventory(a)	22,849
Intangible assets(b)	121,174
Assumed liability(c)	(47,213)
Net identifiable assets	98,810
Goodwill arising on acquisition(d)	29,897
Total acquisition cost	126,707

NOTE 5: - BUSINESS COMBINATIONS (CONT.)

(a) Inventory was valued at cost which represent its fair value.

(b) The following table details the intangible assets identified

	Fair value USD in thousands
Customer Relations (1)	33,514
Intellectual property (2)	79,141
Assumed contract manufacturing agreement (3)	8,519
Total Intangible assets	121,174

(1) Customer Relations represents its fair value (Level 3) at the acquisition date, based on an Multi Period Excess Earnings Method ("MPEEM"). In measuring the Customer Relations the Company used an appropriate risk-adjusted discount rate of 11 % and churn rate of 5%.

(2) Intellectual property represents its fair value (Level 3) at the acquisition date, based on a Relief from Royalties ("RFRM") Method. In measuring the Intellectual property, the Company used an appropriate risk-adjusted discount rate of 11 % and Royalties rate of 15.2%.

(3) Assumed contact manufacturing agreement represents its fair value (Level 3) at the acquisition date, based on With and Without method. Under the With and Without method the value of an intangible asset is calculated by comparing the cash-flow in situation where the valued asset is part of the business versus the cash-flow in situation where the asset is not part of the business. The Company used an appropriate risk-adjusted discount rate of 11 %.

(c) Pursuant to the Saol APA, the Company assumed certain of Saol's liabilities for the future payment of royalties (some of which are perpetual) and milestone payments to third party subject to the achievement of corresponding CYTOGAM related net sales thresholds and milestones. The fair value of such assumed liabilities at the acquisition date was estimated at $47,213 thousand, which was calculated based on the Option Pricing Method (OPM), Monte Carlo Simulation, and discounted cash flow using a discount rate in the range of 2.25 % and 11 % and the volatility of 10.8-14.2 %.

Such assumed liabilities includes:

- Royalties:10 % of the annual global net sales of CYTOGAM up to $ 25,000 thousand and 5 % of net sales that are greater than $ 25,000 thousand, in perpetuity; 2 % of the annual global net sales of CYTOGAM in perpetuity; and, 8 % of the annual global net sales of CYTOGAM for period of six years following the completion of the technology transfer of the manufacturing of CYTOGAM to the Company, subject to a maximum aggregate of $ 5,000 thousand per year and for total amount of $30,000 thousand throughout the entire six years period.

- Sales milestones: $1,500 thousand in the event that the annual net sales of CYTOGAM in the United States market exceeds $18,766 thousand during the twelve months period ending June 30, 2022; and, $1,500 thousand in the event that the annual net sales of CYTOGAM in the United States market exceeds $18,390 thousand during the twelve months period ending June 30, 2023.

- Milestone: $8,500 thousand upon the receipt of FDA approval for the manufacturing of CYTOGAM at Company's manufacturing facility.

NOTE 5: - BUSINESS COMBINATIONS (CONT.)

(d) The goodwill arising on acquisition is attributed to the expected benefits from the synergies of the combination of the activities of the Company and the acquired business. The goodwill recognized is not expected to be deductible for income tax purposes.

The Company recognized the fair value of the assets acquired and liabilities assumed in the business combination according to a provisional measurement. The purchase consideration and the fair value of the acquired assets and liabilities may be adjusted within 12 months from the acquisition date. At the date of final measurement, adjustments are generally made by restating comparative information previously determined provisionally.

The Company incurred acquisition – related cost of $1,094 thousand related mainly to legal and other consulting fees. These costs were recorded in general and administrative expenses in the statement of profit and loss during 2021.

NOTE 6: - CASH AND CASH EQUIVALENTS

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Cash and deposits for immediate withdrawal	$ 15,371	$ 20,075
Cash equivalents in USD deposits (1)	-	47,011
Cash equivalents in NIS deposits (2)	3,216	3,111
Total Cash and Cash Equivalents	$ 18,587	$ 70,197

(1) The deposits bear interest of 0.21%-0.52% per year, as of December 31, 2020.
(2) The deposits bear interest of 0.28% per year, as of December 31, 2021 and 0.18% per year, as of December 31, 2020.

NOTE 7: - SHORT-TERM INVESTMENTS

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Fair value through other comprehensive income	$ -	$ -
Bank deposits in USD (1)	-	39,069
Total Short-Term Investments	$ -	$ 39,069

(1) The deposits bear interest of 0.63%-0.89% r, as of December 31, 2020.

NOTE 8: - TRADE RECEIVABLES, NET

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Open accounts:		
In NIS	$ 16,093	$ 10,756
In USD	18,736	11,219
	$ 34,829	$ 21,975
Checks receivable	333	133
	$ 35,162	$ 22,108
Less allowance for doubtful accounts(1)		-
Total Trade receivables, net	$ 35,162	$ 22,108

(1) As of December 2021and, 2020 no allowance for doubtful accounts was recognized.

NOTE 8: - TRADE RECEIVABLES, NET (CONT.)

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, 2021	$ 33,454	$ 593	$ 572	$ 122	$ 381	$ 40	$ 35,162
December 31, 2020	$ 20,389	$ 1,180	$ 7	$ 6	$ -	$ 526	$ 22,108

(1) Subsequent to December 31, 2021, $1620 thousand from the past due debt was collected.

NOTE 9: - OTHER ACCOUNTS RECEIVABLES

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Prepaid expenses	$ 3,992	$ 2,105
Inventory designated for R&D activities	4,407	1,026
Government authorities	220	735
Derivatives financial instruments mainly measured at fair value through other comprehensive income	73	448
Accrued income	173	202
Other	7	8
Total Other Accounts Receivables	$ 8,872	$ 4,524

NOTE 10: - INVENTORIES

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Finished products	$ 36,270	$ 13,459
Purchased products	6,251	6,751
Work in progress	8,082	8,389
Raw materials	16,820	13,417
Total Inventories	$ 67,423	$ 42,016

(1) During the years 2021, 2020 and 2019, the Company recognized, at cost of revenues, an impairment for inventories carried at net realizable value totaled of $2,982 thousands, $1,440 thousands and $334 thousands, respectively.

(2) The inventory balance as of December 31, 2021 includes $20,040 thousand of finished products and raw materials which were obtained as part of the business combination. Refer to note 5b for further details

NOTE 11: - PROPERTY, PLANT AND EQUIPMENT

a. Composition and movement:

2021

	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, 2021	$ 33,658	31,299	31	8,112	1,139	74,239
Additions	885	2,140	-	1,260	45	4,329
Balance as of December 31, 2021	34,543	33,439	31	9,371	1,184	78,568
Accumulated Depreciation						
Balance as of January 1, 2021	20,049	22,110	20	5,961	420	48,560
Depreciation	1,042	1,694	3	847	115	3,701
Balance as of December 31, 2021	21,091	23,804	23	6,808	535	52,261
Depreciated cost as of December 31, 2021	$ 13,451	$ 9,635	$ 8	$ 2,563	$ 649	$ 26,307

(1) Including labor costs charged in 2021 to the cost of facilities, machinery and equipment in the amount of $775 thousands.

NOTE 11: - PROPERTY, PLANT AND EQUIPMENT (CONT.)

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.

b. As for liens, refer to Note 20.

c. Leasing rights of land from the Israel land administration.

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Under finance lease	$ 1,150	$ 980

Kamada Assets 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. As part of a new outline which were approved during 2021 the plant area was adjusted to 14,880 m². The amount 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 12: - INTANGIBLE ASSETS, GOODWILL AND OTHER LONG TERM ASSETS

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Intangible Assets and Goodwill	153,592	1,492
Long term pre-paid expenses	71	81
Total Other Long-Term Assets	$ 153,663	$ 1,573

1. Intangible Assets:

(a) Composition and movement

	Intellectual property	Customer Relationships	Goodwill	Other Intangibles (1)	Total
	U.S. Dollars in thousands				
Cost:					
Balance as of January 1, 2020	-	-	-	1,492	1,492
Purchases				490	490
Business combination (b)	80,103	33,514	30,313	8,519	152,449
Balance as of December 31, 2021	$ 80,103	$ 33,514	$ 30,313	$ 10,501	$ 154,431
Accumulated amortization and impairment:					
Balance as of January 1, 2020	-	-	-	-	-
Amortization recognized in the year	477	179	-	183	839
Balance as of December 31, 2020	477	179	-	183	839
Amortized cost at December 31, 2021	$ 79,626	$ 33,335	$ 30,313	$ 10,318	$ 153,592

(1) Includes Assumed contract manufacturing agreement and distribution right of certain therapeutic products to be distributed in Israel, subject to Israeli Ministry of Health ("IL MOH") marketing authorization. The Company was required to make certain upfront and milestone payments on account of such distribution rights. These payments are accounted for as long-term assets through obtaining IL MOH marketing authorization and will subsequently be amortized during the expected distribution right's useful life.

(b) Acquisitions during the year:

Intellectual property, Customer Relations and Assumed Contract Manufacturing agreement which were acquired pursuant the Saol APA. See Note 5.

(c) Amortization:

Amortization expenses of intangible assets are classified in statement of profit or loss as follows:

	Year ended December 31,		
	2021	2020	2019
	USD in thousands		
Cost of Goods sold	574	-	-
Selling and marketing expenses	265	-	-
	839	-	-

NOTE 12: - INTANGIBLE ASSETS, GOODWILL AND OTHER LONG TERM ASSETS (CONT.)

(d) Allocation of goodwill to cash-generating units

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Proprietary	30,313	-

All the Goodwill recognized in 2021 was attributed to the Proprietary segment. See note 5.

The recoverable amount of the Proprietary segment was determined based on the value in use which is calculated as the expected estimated future cash flows from this cash-generating unit, as determined for the next five years and approved by the Company's management. The discount rate of the cash flows is 11 %, The estimated recoverable amount of the unit was higher than its carrying amount, and therefore there was no need to provide for impairment.

Sensitivity test preformed with changing the discount rate and the growth rate did not change the result.

NOTE 13: - TRADE PAYABLES

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Open debts mainly in USD	$ 7,354	$ 3,523
Open debts in EUR	9,174	5,413
Open debts in NIS	8,576	7,174
Total Trade Payables	$ 25,104	$ 16,110

NOTE 14: - OTHER ACCOUNTS PAYABLES

a. Composition:

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Employees and payroll accruals	$ 6,348	$ 7,031
Government grants (b)	207	222
Accrued Expenses and Others	587	294
Total Other Accounts Payables	$ 7,142	$ 7,547

b. Government grants:

Presented in the statement of financial position and Profit or Loss and Other Comprehensive Income:

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Current Assets	3	184
Current liability	207	222
Royalties paid during the year	-	-
Expense (income) carried to profit or loss	$ (29)	$ (279)

NOTE 15: - LOANS AND FINANCIAL LIABILITIES

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Bank loans(1)	20,038	274
Less current maturities of bank loans	2,631	238
Total Long term bank loans	$ 17,407	$ 36

1. Bank loan:

On November 15, 2021, the Company secured a $40,000 thousand credit facility from Bank Hapoalim, an Israeli bank. The credit facility comprised of the following:

(1) A $20,000 thousand long-term loan. The loan baring an interest at a rate of SOFR (Secured Overnight Financing Rate) +2.18% and is payable over 54 equal monthly installments commencing June 16, 2022; and

(2) A $20,000 thousand short-term revolving credit facility from an Israeli bank. The credit facility bares an interest at a rate of SOFR +1.75%, or a commitment fee of 0.2% calculated over the unutilized balance of the facility. As of December 31, 2021, the Company did not utilize such facility.

Pursuant to the loan and credit facility agreement, the Company is required to meet the following financial covenants for the years ending December 31, 2022, and onwards:

(1) The Shareholder's Equity shall at no time be less than 30% of the Total Assets; examined on a quarterly basis;

(2) The Shareholder's Equity shall at no time be less than $120,000 thousand; examined on a quarterly basis;

(3) The ratio between:(a) the short term financial debt less current maturities of long term debt (in as much as such are included therein); and (b) the Working Capital as such term is defined in the loan agreement, shall at no time exceed 0.8; examined on a quarterly basis; and

(4) The ratio between: (a) the EBITDA as such term is defined in the loan agreement; and (b) the current maturities of long term debt plus out of pocket financial expenses net, reported in the course of four consecutive quarters immediately preceding the examination date, shall not be less than 1.1 during each of the years 2022 and 2024 and not less than 1.25 in the year 2025 and onwards; examined on an annual basis.

Bank loans borrowed prior to 2021 are payable over 60 equal monthly installments. The loans bear fixed interest rate in the range of 3.15% -3.55%. The remaining balance as of December 31, 2021 is $38 thousands.

See Note 19 regarding pledge information related to the bank loans.

NOTE 15: - LOANS AND FINANCIAL LIABILITIES (CONT.)

b. Financial liabilities through business combination

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Contingent consideration (2)	21,995	-
Assumed liabilities (3)	61,915	-
Less current maturities	(17,986)	-
Total Long term Contingent consideration and assumed liabilities	$ 43,929	$ -

(2) At December 31, 2021 the fair value of the contingent consideration total $21,995 thousand. The increase in the amount of $290 thousands reflects the changes in the value of the liability since the date of acquisition and was recognized as financing expenses in the statement of profit and loss. Refer to Note 5b and Note 17 for details on the contingent consideration.

(3) The assumed liabilities are measured at amortized cost. The increase of $704 thousands reflects the changes in time value due to and changes in expected payments since the date of acquisition. The increase was recognized as financing expenses in the statement of profit and loss. Refer to Note 5 and Note 17 for details on the assumed liabilities.

NOTE 16: - LEASES

Leases

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 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

2021

	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, 2021	$ 2,599	$ 821	$ 20	$ 3,440	$ 4,665
Additions to right -of -use assets		845		845	845
Termination lease		(125)		(125)	(125)
Depreciation expense	(433)	(628)	(5)	(1,068)	
Exchange rate differences					150
Repayment of lease liabilities					(1,221)
As of December 31, 2021	$ 2,165	$ 913	$ 15	$ 3,092	$ 4,314

(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 1.75%-4.6% evaluated based on credit risk, terms of the leases and other economic variables.
During 2021 the company recognized $253 thousand as interest expenses on lease liabilities.
During 2021 the total cash outflow for leases was $1,474 thousand.

NOTE 16: - LEASES (CONT.)

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
Lease termination		(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.
During 2020 the company recognized $190 thousand as interest expenses on lease liabilities.
During 2020 the total cash outflow for leases was $1,296 thousand.

Maturity analysis of the Company's lease liabilities (including interest):

December 31, 2021

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Lease liabilities (including interest)	$ 1,307	$ 1,100	$ 849	$ 1,485	$ 31	$ 4,772

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

NOTE 16: - 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 has reasonable certainty that the extension option will be exercised in order to avoid a significant adverse impact to its operating activities.

NOTE 17: - 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,	
	2021	2020
	U.S. Dollars in thousands	
Financial assets		
Financial assets at fair value through profit or loss:		
Foreign exchange forward contracts	$ -	$ -
Financial assets at fair value through other comprehensive income:		
Cash flow hedges	73	457
Marketable debt securities	-	-
Total Financial assets at fair value through other comprehensive income:	$ 73	$ 457
Financial assets at cost:		
Cash and cash equivalent	18,587	70,197
Short term bank deposits	-	39,069
Total Financial assets at cost	$ 18,587	$ 109,266
Total financial assets	$ 18,660	$ 109,723
Financial liabilities		
Financial liabilities at fair value through profit or loss:		
Contingent consideration in business combination	21,995	-
Foreign exchange forward contracts	$ -	$ 9
	21,995	
Financial liabilities measured at amortized cost:		
Assumed liabilities through business combination	61,915	-
Bank loans	20,038	274
Leases	4,314	4,665
Total Financial liabilities measured at amortized cost:	$ 86,267	$ 4,939
Total financial and lease liabilities	$ 108,262	$ 4,948

NOTE 17: - 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's management and specifically that of the 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, 2021 and 2020, 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 17f. 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, 2020, 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, 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 8 for additional information.

NOTE 17: - 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, 2021 and 2020 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 17f. below).

d) Interest rate risk:

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company's exposure to the risk of changes in market interest rates relates primarily to the Company's long-term liabilities with floating interest.

3. Liquidity risk

The table below summarizes the maturity profile of the Company's financial liabilities based on contractual undiscounted payments:

December 31, 2021

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Trade payables	$ 25,104					$ 25,104
Assumed liabilities (1)	17,986	11,203	4,671	7,598	20,457	61,915
Other accounts payables	7,142					7,142
Bank loans (including interest)	3,049	4,773	4,677	8,689	-	21,188
Lease liabilities (including interest)	1,307	1,100	849	1,485	31	4,772
	$ 54,588	$ 17,076	$ 10,197	$ 17,772	$ 20,488	$ 120,121

(1) Due the nature of the account which include infinite payments for royalties and milestones to third party the assumed liabilities reflect the discounted amount. see Note 19e

NOTE 17: - FINANCIAL INSTRUMENTS (CONT.)

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

Changes in liabilities arising from financing activities

	January 1, 2021	Payments	Foreign exchange movement	New loans and leases	Business combination	Revaluation	Write off	December 31, 2021
	U.S. Dollars in thousands							
Contingent consideration (1)	-	-	-	-	21,705	290	-	21,995
Assumed liabilities	-	-	-		61,211	704	-	61,915
Bank loans	$ 274	(205)	(31)	20,000			-	$ 20,038
Leases	4,665	(1,221)	150	845			(125)	4,314
Total	$ 4,939	$ (1,426)	$ 119	$ 20,845	$ 82,916	$ 994	$ (125)	$ 108,262

(1) The contingent consideration fair value as of December 31,2021 was based on an Option Pricing Method (OPM), "Monte Carlo Simulation" model. In measuring the contingent consideration liability, the Company used an appropriate risk- adjusted discount rate of 10.5 % and volatility of 10.6 %. totaled $21,995 thousands.

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,	
	2021	2020	2021	2020
	U.S. Dollars in thousands			
Assumed liabilities	61,915	-	61,915	-
Bank loans	20,038	274	19,502	278
Leases	4,314	4,665	4,608	4,935
Total Financial liabilities	$ 108,262	$ 4,939	$ 108,020	$ 5,213

The fair value of the bank loans ,leases and the assumed liabilities was based on standard pricing valuation model such as a discounted cash-flow model which considers the present value of future cash flows discounted by an 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 17: - 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	Level 3 (1)
	U.S. Dollars in thousands		
December 31, 2021			
Derivatives instruments	-	73	
Contingent consideration			(21,995)
	$ -	$ 73	$ (21,995)

(1) For changes in Contingent liability see above

	Level 1	Level 2
	U.S. Dollars in thousands	
December 31, 2020		
Derivatives instruments	-	448
	$ -	$ 448

During 2021 and 2020 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 17: - FINANCIAL INSTRUMENTS (CONT.)

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Sensitivity test to changes in Interest rate risk		
Gain (loss) from change:		
1% increase in in basis points of SOFR	$ (23)	$ -
1% decrease in in basis points of SOFR	$ 22	$
Sensitivity test to changes in foreign currency:		
Gain (loss) from change:		
5% increase in NIS	$ (30)	$ (24)
5% decrease in NIS	$ 30	$ 24
5% increase in Euro	$ (450)	$ (552)
5% decrease in Euro	$ 450	$ 552

e. Linkage terms of financial liabilities by groups of financial instruments pursuant to IFRS 9:

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
In NIS:		
Bank loans measured at amortized cost	$ 38	$ 274
Leases measured at amortized cost	4,314	4,665
	$ 4,352	$ 4,939
In USD:		
Contingent consideration at fair value through profit or loss	21,995	-
Assumed liabilities measured at amortized cost	61,915	-
Bank loans measured at amortized cost	20,000	-
	$ 103,910	$ -

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, 2021 the fair value of the derivative instruments not designated as hedging was financial assets of $20 thousands. The open transactions for those derivatives were in an amount of $19,906 thousands.

Cash flow hedges:

As of December 31, 2021, 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, 2021 the fair value of the derivative instruments designated as hedge accounting was an asset of $53 thousands. The open transactions for those derivatives were in an amount of $226 thousands.

Cash flow hedges of the expected salaries and suppliers expenses in December 31, 2021 was estimated as effective and accordingly a net unrecognized income was recorded in other comprehensive income in the amount of $303 thousands net. The ineffective portion were allocated to finance expense.

NOTE 18: - 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 2021, 2020 and 2019 were $1,023 thousands, $1,299 thousands and $1,102 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,		
	2021	2020	2019
	U.S. Dollars in thousands		
Current service cost	$ 281	$ 264	$ 282
Past service cost(1)	415		
Interest expenses, net	23	23	23
Total employee benefit expenses	716	287	305
Actual return on plan assets	$ 349	$ 35	$ 158

(1) During 2021 the Company paid employees an increased compensation due to downsizing program.

NOTE 18: - EMPLOYEE BENEFIT LIABILITIES, NET (CONT.)

The expenses are presented in the Statement of Comprehensive income (loss) as follows

	Year Ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
Cost of revenues	$ 499	$ 195	$ 201
Research and development	90	45	62
Selling and marketing	62	22	16
General and administrative	65	25	26
	$ 716	$ 287	$ 305

4. The plan liabilities, net:

	December 31,	
	2021	2020
	U.S. Dollars in thousands	
Defined benefit obligation	$ 5,434	$ 5,606
Fair value of plan assets	4,154	4,200
Total liabilities, net	$ 1,280	$ 1,406

5. Changes in the present value of defined benefit obligation

	2021	2020
	U.S. Dollars in thousands	
Balance at January 1,	$ 5,606	$ 5,058
Interest costs	84	84
Current service cost	281	264
Past service cost	415	-
Benefits paid	(1,309)	(102)
Demographic assumptions	10)	(3)
Financial assumptions	33)	(124)
Past Experience	149	33
Currency Exchange	165	396
Balance at December 31,	$ 5,434	$ 5,606

6. Plan assets

a) Plan assets

Plan assets comprise assets held by long-term employee benefit funds and qualifying insurance policies.

NOTE 18: - EMPLOYEE BENEFIT LIABILITIES, NET (CONT.)

b) Changes in the fair value of plan assets

	2021	2020
	U.S. Dollars in thousands	
Balance at January 1,	$ 4,200	$ 3,789
Expected return	62	61
Contributions by employer	189	187
Benefits paid	(780)	(102)
Demographic assumptions	0	0
Financial assumptions	0	0
Past Experience	362	(29)
Currency exchange	121	294
Balance at December 31,	$ 4,154	$ 4,200

7. The principal assumptions underlying the defined benefit plan

	2021	2020	2019
		%	
Discount rate of the plan liability	3.1	1.8	2.8
Future salary increases	3.0	3.0	3.1

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 $266 thousands or increase by $310 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 $294 thousands or decrease by $252 thousands, respectively.

NOTE 19: - 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").

Through December 31, 2021, the Company accounted for as income all of the $45 million associated with the 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.

On March 31, 2021, the Company entered into an amendment to the Technology License Agreement with Takeda with respect to Glassia. Pursuant to the amendment the Company will transfer to Takeda the GLASSIA U.S. Biologics License Application (BLA). In consideration for the BLA transfer, the Company will receive a $2 million payment from Takeda.

During 2021 the Company terminated the production and supply of GLASSIA to Takeda and Takeda initiated its own production of GLASSIA for distribution in the Territory. Accordingly, commencing 2022, Takeda will pay royalties to the Company 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 19: - 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 PARI 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.

c. In July 2011, the Company entered into a strategic collaboration agreement with Kedrion Biopharma ("Kedrion") 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 authorization 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 U.S. plasma collection 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. As of December 31, 2021, the parties did not enter into a definitive agreement.

NOTE 19: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

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 Saol to manufacture CYOTGAM. 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 a result of the consummation of the Saol transaction as detailed below, which included the acquisition of all rights relating to CYTOGAM, the previous engagement with Saol with respect to this product expired.

On November 22, 2021, the Company entered into the Saol APA for the acquisition of a portfolio of four FDA-approved plasma-derived hyperimmune commercial products. The Product are CYTOGAM, HEPAGAM B, VARIZIG AND WINRHO SDF.

Under the terms of the APA, the Company paid Saol a $95 million upfront payment, and agreed to pay up to an additional $50 million of contingent consideration subject the achievement of sales thresholds for the period commencing on the Acquisition Date and ending on December 31, 2034. The Company may be entitled for up to $3 million credit deductible from the contingent consideration payments due for the years 2023 through 2027, subject to certain conditions as defined in the agreement between the parties.

In addition, the Company acquired inventory valued at $14.2 million and agreed to pay the consideration to Saol in ten quarterly installments of $1.5 million, each or the remaining balance at the final installment.

As part of the acquisition, the Company assumed certain of Saol's liabilities for the future payment of royalties (some of which are perpetual) and milestone payments to third party subject to the achievement of corresponding CYTOGAM related net sales thresholds and milestones. The fair value of such assumed liabilities at the acquisition date was estimated at $47.2 million, which was calculated based on the Option Pricing Method (OPM), Monte Carlo Simulation, and discounted cash flow using a discount rate in the range of 2.25 % and11% and the volatility of 10.8-14.2 %.

Such assumed liabilities include:

- Royalties:10 % of the annual global net sales of CYTOGAM up to $25 million and 5 % of net sales that are greater than $25 million, in perpetuity; 2% of the annual global net sales of CYTOGAM in perpetuity; and, 8% of the annual global net sales of CYTOGAM for period of six years following the completion of the technology transfer of the manufacturing of CYTOGAM to the Company, subject to a maximum aggregate of $5 million per year and for total amount of $30 million throughout the entire six years period.

- Sales milestones: $1.5 million in the event that the annual net sales of CYTOGAM in the United States market exceeds $18.8 million during the twelve months period ending June 30, 2022; and, $1.5 million in the event that the annual net sales of CYTOGAM in the United States market exceeds $18.4 million during the twelve months period ending June 30, 2023.

- Milestone: $8.5 million upon the receipt of FDA approval for the manufacturing of CYTOGAM at Company's manufacturing facility.

To partially fund the acquisition costs, the Company secured a $40 million financing facility from an Israeli bank which comprised of a $20 million five-year loan and a $20 million short-term revolving credit facility. Refer to Note 15

In connection with the acquisition, The Company entered into a transition services agreement with Saol, which defines the services and support to be provided by Saol to the Company for a defined period (including, U.S reporting, medical inquiries, transfer planning, logistics management, distribution and QC complaints). The term of the transition services agreement for most services is estimated between three to six months. The cost for services provided under the transition services agreement is based on the actual work to be performed by Saol, with monthly workload adjustments, and pass-through costs.

As of December 31, 2021, the Company recognized an asset in respect of costs of fulfilling contracts on the amount of $ 5,561 thousands. No amortization or impairment losses was recognized.

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. Subsequent to December 31, 2021, the agreement was extended to include additional two biosimilar products.

g. On January 14, 2021, the Company entered into an agreement with undisclosed international pharmaceutical companies to commercialize one of the distribution products, in Israel. Pursuant to the agreement the Company is obligate to pay Royalties on the amount of 24% out of the Net revenue from the sale of the product in the Israeli market.

NOTE 20: - GUARANTEES AND CHARGES

a. The Company provided a bank guarantees in the amount of $ 287 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 asset as collateral against loan, in the original amount of NIS 1,000 thousand ($ 321 thousand) received to fund the purchase of such assets.
As of December 31, 2021, the loan balance is $38 thousand. See note 15.

c. In connection with the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF from Saol, the Company secured $40,000 thousand of debt facility from an Israeli bank, the Company undertook not to create any first ranking floating charge over all or materially all of its property and assets in favor of any third party unless certain terms, as defined in the loan agreement has been satisfied.

NOTE 21: - EQUITY

a. share capital

	December 31, 2021		December 31, 2020	
	Authorized	Outstanding	Authorized	Outstanding
Ordinary shares of NIS 1 par value	70,000,000	44,799,794	70,000,000	44,742,963

b. Movement in share capital:

Issued and outstanding share capital:

	Number of shares
Balance as of January 1, 2020	40,353,101
Issue of shares	4,166,667
Exercise of options into shares	164,867
Vesting of restricted shares	58,328
Balance as of December 31, 2020	44,742,963
Issue of shares	-
Exercise of options into shares	4,293
Vesting of restricted shares	52,538
Balance as of December 31, 2021	44,799,794

Ordinary shares of NIS 1 par value

NOTE 21: - EQUITY (CONT.)

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 2021 and 2020, 28,672 and 449,093 share options, respectively, were exercised, on a net exercise basis, into 4,293 and 164,867 ordinary shares of NIS 1 par value each and 52,538 and 58,328 restricted share units were vested, respectively. The total consideration from such exercise totaled $17 thousand for each of 2021 and 2020.

For additional information regarding options and restricted shares granted to employees and management in 2021, refer to Note 22 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 22: - 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 vesting 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		
	2021	2020	2019
	U.S. Dollar in thousands		
Cost of revenues	$ 69	$ 244	$ 364
Research and development	79	184	254
Selling and marketing	34	39	63
General and administrative	347	510	482
Total share-based compensation	$ 529	$ 977	$ 1,163

b. Share options granted:

During the year ended December 31, 2021, no grants of options or RS were made to the Company's Chief Executive Officer ("CEO"), Board of Directors members, employees or management.

c. Extension of exercise terms of stock option:

On October 12, 2021, the Company's Board of Directors approved an extension of the exercise term of 88,900 outstanding options for one year period from October 27, 2021 till October 2022. The fair value of such term extension estimated based on the Binomial Model, is $47 thousands.

NOTE 22: - SHARE-BASED PAYMENT (CONT.)

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:

	2021		2020		2019	
	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	1,660,958	20.38	2,336,554	27.87	2,445,597	29.99
Granted	-	-	382,000	24.36	443,800	20.64
Exercised	(28,672)	16.93	(449,093)	18.49	(67,470)	32.30
Forfeited	(127,608)	20.29	(608,503)	51.68	(485,373)	16.98
Outstanding at end of year	1,504,678	20.65	1,660,958	20.38	2,336,554	27.87
Exercisable at end of year	1,067,363	19.78	799,640	18.97	1,412,023	33.17
The weighted average remaining contractual life for the share options		3.33		4.18		3.39

The range of exercise prices for share options outstanding as of December 31, 2021and 2020 were NIS 14.82- NIS 29.68. Exercise is by net exercise method.

NOTE 22: - SHARE-BASED PAYMENT (CONT.)

f. The following table lists the number of RSs and changes in RSs grants during the year:

	Number of RSs		
	2021	2020	2019
Outstanding at beginning of year	104,519	145,896	139,706
Granted	-	30,000	69,725
End of restriction period	(52,538)	(58,328)	(18,643)
Forfeited	(2,420)	(13,049)	(44,892)
Outstanding at end of year	49,561	104,519	145,896
The weighted average remaining contractual life for the restricted share	3.40	4.39	2.78

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:

	2021[(1)]	2020	2019
Dividend yield (%)	-	-	-
Expected volatility of the share prices (%)	-	30-55	23-41
Risk-free interest rate (%)	-	0.01 – 0.58	0.3 – 1.7
Contractual term of up to (years)	-	6.5	6.5
Exercise multiple	-	2	2
Weighted average share prices (NIS)	-	20.28-28.98	19.17-19.65
Expected average forfeiture rate (%)	-	1.9-5.9	2-6

(1) During the year ended December 31, 2021, no grants of options or RS were made

NOTE 22: - 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 23: - 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 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 23: - 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. Pursuant to the Tax Ruling, the Year of Election was 2009. The Company obtained a subsequent Tax Ruling also noting 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 23: - 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).

Amendment 73 to the Encouragement Law also prescribes special tax tracks for technological enterprises, which became effective in 2017, as follows: Preferred technological enterprise, which is defined in the Encouragement Law as a company that owns the enterprise and is a member of a group whose total consolidated revenues are less than NIS 10 billion in the tax year, will be subject to tax at a rate of 12% on profits deriving from intellectual property (in development area A - a tax rate of 7.5%).Special preferred technological enterprise which is a member of a group whose total consolidated revenues exceed NIS 10 billion in the tax year will be subject to tax at a rate of 6% on preferred income from the enterprise, regardless of the enterprise's geographical location.Any dividends distributed to "foreign companies", as defined in the Encouragement Law, deriving from income from the technological enterprises will be subject to tax at a rate of 4%, subject to the conditions prescribed in Section 51Z to the Encouragement Law.

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 23: - 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 Israeli parliament passed a 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 parliament 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 24% in 2017 and 23% since 2018.

NOTE 23: - TAXES ON INCOME (CONT.)

c. Tax assessments

The Company has finalized tax assessments through the end of tax year 2016.

c. Taxation of the subsidiaries:

Kamada Inc and Kamada Plasma LLC are incorporated in the United States and is subject U.S. Federal and State tax laws. The two subsidiaries are filling a joint tax return

On December 22, 2017, the Tax Cuts and Jobs Act (the "Act") was signed into law. The Act reduces the corporate tax rate to 21% from 35%, among other things.

d. Carry forward losses for tax purposes and other temporary differences

As of December 31, 2021, the Company has carried forward losses and other temporary differences in the amount of $ 33,023 thousands. Final tax assessments for the years 2017 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, 2021, 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, 2021 and 2020, 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, 2021, 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.

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 23: - TAXES ON INCOME (CONT.)

g. Composition:

	Statements of financial position December 31,		Statements of profit or loss Year ended December 31,		
	2021	2020	2021	2020	2019
	U.S Dollars in thousands				
Deferred tax liabilities:					
Financial assets measured at fair value through other comprehensive income	-	-			
Revaluation of derivatives	-	-			
Deferred tax assets:					
Carryforward tax losses	-	-	-	(1,330)	(726)
Employee benefits	-	-			
Deferred tax income (expenses)			-	(1,330)	(726)
Deferred tax assets, net	$ -	$ -			

h. Taxes on income

	Year ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
Current taxes	$ 345	$ 95	$ -
Deferred tax expenses (income)	-	1,330	726
Taxes in respect of prior years		-	4
Taxes on income	$ 345	$ 1,425	$ 730

NOTE 23: - TAXES ON INCOME (CONT.)

i. Theoretical tax

2021

The reconciliation between the statutory tax rate and the effective tax rate as recorded in profit or loss, does not provide significant information, and therefore was not presented.

2019-2020

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	Year ended December 31 2019
	U.S. Dollars in thousands	U.S. Dollars in thousands
Gain before taxes on income	$ 18,565	$ 22,981
Statutory tax rate	23%	23%
Tax calculated using the statutory tax rate	4,270	5,286
Increase (decrease) in taxes resulting from permanent differences - the tax effect:		
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	(3,082)	(3,747)
Tax exempt income, income subject to special tax rates and nondeductible expenses and other	(303)	(105)
Difference between measurement basis of income/expenses for tax purposes and measurement basis of income/expenses for financial reporting purposes	441	-
Increase in unrecognized tax losses in the year	-	(352)
Prior year taxes	-	4
Other	99	-
Tax on income	$ 1,425	$ 730
Effective tax rate	7.7%	3.2%

NOTE 24: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF PROFIT AND LOSS

a. Additional information about revenues

	Year Ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
Revenues from major customers each of whom amount to 10% or more, of total revenues			
Customer A[1][2]	$ 31,936	$ 65,081	$ 68,138
Customer B[3]	12,357	13,793	14,454
Customer C[2]	11,947	18,290	16,369
	$ 56,240	$ 97,163	$ 98,961

(1) For additional information regarding the aggregate amount of the transaction price allocated to the performance obligations that are unsatisfied, refer to note 19a.

(2) Revenue is attributed to the Proprietary segment.

(3) Revenue is attributed mainly to the Distribution segment.

b. Revenues based on the location of the customers, are as follows:

	Year Ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
U.S.A and North America	$ 49,763	$ 84,949	$ 84,572
Israel	35,774	36,144	31,959
Europe	5,677	4,461	4,701
Latin America	9,127	6,867	3,792
Asia	3,167	766	2,067
Others	134	59	96
Total Revenue	$ 103,642	$ 133,246	$ 127,187

NOTE 24: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF PROFIT AND LOSS (CONT.)

c. Cost of goods sold

	Year Ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
Cost of materials (1)	$ 63,945	$ 54,745	$ 69,766
Salary and related expenses	17,486	17,957	16,941
Subcontractors	4,892	4,876	4,451
Depreciation and amortization	3,627	3,248	2,991
Energy	1,464	1,626	1,551
Other manufacturing expenses	1,298	575	712
	92,712	83,027	96,412
Decrease (increase) in inventories	(19,398)	2,667	(18,962)
Total Cost of goods sold	$ 73,314	$ 85,694	$ 77,450

(1) costs of materials for the year ended December 31, 2021 includes $24,282 of inventory obtained in connection with the business combination. Refer to Note 5b for further detail on the business combination.

d. Research and development

	Year Ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
Salary and related expenses	$ 5,076	$ 6,045	$ 5,897
Subcontractors	3,656	4,794	5,196
Materials and allocation of facility costs	1,896	1,682	966
Depreciation and amortization	616	725	663
Others	113	363	337
Total Research and development	$ 11,357	$ 13,609	$ 13,059

For additional information regarding government grant refer to Note 13(b)

e. Selling and marketing

	Year Ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
Salary and related expenses	$ 1,930	1,639	1,467
Marketing support	136	144	103
Packing, shipping and delivery	912	750	504
Marketing and advertising	1,193	586	788
Registration and marketing fees	1,262	934	917
Others	845	465	591
Total Selling and marketing	$ 6,278	$ 4,518	$ 4,370

NOTE 24: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF PROFIT AND LOSS (CONT.)

f. General and administrative

	Year Ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
Salary and related expenses	$ 3,853	$ 3,870	3,475
Employees welfare	1,259	978	1,296
Professional fees and public company expense	4,982	3,055	2,162
Depreciation, amortization and impairment	875	779	717
Communication and software services	977	924	799
Others	690	533	745
Total General and administrative	$ 12,636	$ 10,139	$ 9,194

g. Financial expense(income)

	Year Ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
Financial income			
Interest income and gains from marketable securities	$ 295	$ 1,027	$ 1,146
Financial expense			
Fees and interest paid to financial institutions	1,277	266	293
Financial income and (expense)			
Derivatives instruments measured at fair value	(565)	(1,097)	(512)
Translation differences of financial assets and liabilities	358	(438)	(139)
Bond securities measured at fair value	-	102	(5)
Total Financial expense(income)	$ (1,189)	$ (672)	$ 197

NOTE 25: - 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,					
	2021		2020		2019	
	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)	44,771,766	$ 118	44,140,771	$ 17,140	40,320,888	$ 22,251
Effect of potential dilutive ordinary shares	130,177	-	449,107	-	260,739	-
For the computation of diluted income (loss)	44,901,943	$ 17,140	44,589,878	$ 17,140	40,581,627	$ 22,251

b. The computation of the diluted income per share for the years ending December 31, 2021, 2020 and 2019 took into account the options and RSs due to their dilutive effect.

NOTE 26: - 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 26: - OPERATING SEGMENTS (CONT.)

b. Reporting on operating segments

	Proprietary Products	Distribution	Total
	U.S. Dollars in thousands		
Year Ended December 31, 2021			
Revenues	$ 75,521	$ 28,121	$ 103,642
Gross profit	$ 27,327	$ 3,001	$ 30,328
Unallocated corporate expenses			(31,024)
Finance income, net			(1,189)
Income before taxes on income			$ (1,885)

	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 thousand		
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 expense, net			197
Loss before taxes on income			$ 22,981

NOTE 27: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES

a. Balances with related parties

	December 31, 2021	December 31, 2020
	U.S. Dollars in thousands	
Trade receivable	$ 1,295	$ 1,429
Other accounts payables	$ 101	$ 129

NOTE 27: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

b. Transactions with employed/directors that accounts as related parties

	Year Ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
Salary and related expenses to those employed by the Company or on its behalf	$ -	$ -	$ 311
Remuneration of directors not employed by the Company or on its behalf	$ 487	$ 506	$ 363
Number of People to whom the Salary and remuneration Refer:			
Related and related parties employed by the Company or on its behalf	-	-	2
Directors not employed by the Company	9	9	7
Total Directors employed and not employed by the Company	9	9	9

c. Transactions with key executive personnel (including non-related parties)

	Year Ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
Short-term benefits	$ 2,791	$ 3,237	$ 3,157
Share-based payment	255	457	506
Total	$ 3,046	$ 3,694	$ 3,663

d. Transactions with related parties

	Year Ended December 31,		
	2021	2020	2019
	U.S. Dollars in thousands		
Revenues	$ 5,356	$ 3,899	$ 2,566
Cost of Goods Sold	$ 51	$ 255	$ 13
Selling and marketing expenses	$ 0	$ 0	$ 257
General and administrative expenses	$ 227	$ 522	$ 447

NOTE 27: - 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, 2021, 2020 and 2019, 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 patients and increasing the overall number of 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, which was at the time 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. The distribution agreement with Khairi was an arm's length transaction. For the years ended on December 31, 2019, 2020 and 2021 there were no sales of product 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, Spider solutions ltd, Emet e&m computing 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 27: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

f. CEO employment terms

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. On October 12, 2021 the Company's Board of Directors approved an amendment to the employment terms of the Company's CEO. Pursuant to the amendment the CEO monthly gross salary increased to NIS 92,400 (or $28,607), effective as of July, 1 2021.

During 2021 the Company accounted for a bonus accrual to the CEO in the amount of $89 thousands.

NOTE 28: - EVENTS SUBSEQUENT TO THE REPORTING PERIOD

a. Notice of Labor Dispute from Employee's Committee

On March 3, 2022, during the course of the Company's negotiations with the Histadrut - General Federation of Labor in Israel (the "**Histadrut**") and the Employees' Committee of Kamada's Beit Kama production facility in Israel (the "**Employee's Committee**"), on the extension of a collective bargaining agreement, the Employee's Committee elected to declare a labor dispute.

In the event that the labor dispute will not be resolved within 15 days of its declaration, the Employee's Committee may take further actions in the form of work sanctions and/or work stoppage.
In November 2018, the Company signed a collective bargaining agreement with the Histadrut and the Employees' Committee, which expired on December 31, 2021. During recent weeks, the Company, the Histadrut and the Employees Committee have been negotiating the renewal of the collective bargaining agreement. While significant progress has been achieved throughout the course of the negotiations, the parties have not reached an agreement to date.

The Company cannot currently predict how the dispute will develop, whether additional actions will be taken by the Employee's Committee or the Histadrut, or whether the labor dispute will have an effect on the Company's financial results. However, at this time, the Company does not anticipate that actions taken will have a material effect on its ability to continue the supply of its products to the market, including those recently acquired four IgG commercial products.

b. Grant of options to the purchase ordinary shares of the Company to employees, executive officers, CEO and Board of Directors members

On February 28, 2022, the Company's Board of Directors approved the grant of options to purchase up to 1,575,050, 400,000 and 270,000 ordinary shares of the Company to employees and executive officers, CEO and Board of Directors members, respectively.

The grant of options to the CEO and the Board of Directors members are subject to the approval of the General Meeting of Shareholders that is expected to take place during 2022.

KAMADA LTD.

THE 2011 ISRAELI SHARE AWARD PLAN

(*In compliance with Amendment No. 132 of the Israeli Tax Ordinance, 2002)

This plan, as amended from time to time, shall be known as Kamada Ltd. 2011 Israeli Share Award Plan (the "**ISAP**").

1. PURPOSE OF THE ISAP

The ISAP is intended to provide an incentive to retain, in the employ of the Company and its Affiliates (as defined below), persons of training, experience, and ability, to attract new employees, directors, consultants, service providers and any other entity which the Board (as defined below) shall decide their services are considered valuable to the Company, to encourage the sense of proprietorship of such persons, and to stimulate the active interest of such persons in the development and financial success of the Company by providing them with opportunities to purchase Shares in the Company, pursuant to the ISAP.

2. DEFINITIONS

For purposes of the ISAP and related documents, including the Award Agreement, the following definitions shall apply:

2.1 **"Affiliate"** means any Employing Company.

2.2 **"Approved 102 Award"** means an Award granted pursuant to Section 102(b) of the Ordinance and held in trust by a Trustee for the benefit of the Grantee.

2.3 "**Award**" means, individually or collectively, a grant under the ISAP of Options or Restricted Shares or any combination thereof.

2.4 **"Board"** means the Board of Directors of the Company.

2.5 "**Capital Gain Award (CGA)**" as defined in Section 5.4 below.

2.6 **"Cause"** means, (i) conviction of any felony involving moral turpitude or affecting the Company; (ii) any refusal to carry out a reasonable directive of the chief executive officer, the Board or the Grantee's direct supervisor, which involves the business of the Company or its Affiliates and was capable of being lawfully performed; (iii) embezzlement of funds of the Company or its Affiliates; (iv) any breach of the Grantee's fiduciary duties or duties of care towards the Company; including without limitation disclosure of confidential information of the Company; and (v) any conduct (other than conduct in good faith) reasonably determined by the Board to be materially detrimental to the Company.

2.7 **"Chairman"** means the chairman of the Committee.

2.8 **"Committee"** means the Company's compensation committee appointed by the Board, which shall consist of no fewer than two members of the Board.

2.9 **"Company"** means Kamada Ltd., an Israeli company.

2.10 **"Companies Law"** means the Israeli Companies Law 5759-1999.

2.11 **"Controlling Shareholder"** shall have the meaning ascribed to it in Section 32(9) of the Ordinance.

2.12 **"Date of Grant"** means, the date of grant of an Award, as set forth in the Grantee's Award Agreement, in accordance with the Board's resolution.

2.13 **"Employee"** means a person who is employed by the Company or its Affiliates, including an individual who is serving as a director or an office holder, but excluding a Controlling Shareholder.

2.14 "**Employing Company**" shall have the meaning ascribed to it in Section 102(a) of the Ordinance.

2.15 **"Expiration Date"** means the date upon which an Award shall expire, as set forth in Section 10.2 of the ISAP.

2.16 **"Fair Market Value"** means as of any date, the value of a Share determined as follows:

(i) If the Shares are listed on any established stock exchange or a national market system, including without limitation the Tel-Aviv Stock Exchange, NASDAQ National Market system, or the NASDAQ SmallCap Market of the NASDAQ Stock Market, the Fair Market Value shall be the closing sales price for such Shares (or the closing bid, if no sales were reported), as quoted on such exchange or system for the last market trading day prior to time of determination, as reported in the Wall Street Journal, or such other source as the Board deems reliable. Without derogating from the above, solely for the purpose of determining the tax liability pursuant to Section 102(b)(3) of the Ordinance, if at the Date of Grant the Shares are listed on any established stock exchange or a national market system or if the Shares will be registered for trading within ninety (90) days following the Date of Grant, the Fair Market Value of a Share at the Date of Grant shall be determined in accordance with the average value of a Share on the thirty (30) trading days preceding the Date of Grant or on the thirty (30) trading days following the date of registration for trading, as the case may be;

(ii) If the Shares are regularly quoted by a recognized securities dealer but selling prices are not reported, the Fair Market Value shall be the mean between the high bid and low asked prices for the Shares on the last market trading day prior to the day of determination, or;

(iii) In the absence of an established market for the Shares, the Fair Market Value thereof shall be determined in good faith by the Board.

2.17 **"Grantee"** means a person who receives or holds an Award under the ISAP.

2.18 **"ISAP"** means this 2011 Israeli Share Award Plan as may be amended from time to time.

2.19 "**ITA**" means the Israeli Tax Authorities.

2.20 **"Non-Employee"** means a consultant, adviser, service provider, Controlling Shareholder or any other person who is not an Employee.

2.21 **"Ordinary Income Award (OIA)"** as defined in Section 5.5 below.

2.22 **"Option"** means an option to purchase one or more Shares of the Company pursuant to the ISAP.

2.23 **"102 Award"** means any Award granted to Employees pursuant to Section 102 of the Ordinance.

2.24 **"3(i) Award"** means any Award granted pursuant to Section 3(i) of the Ordinance to any person who is Non- Employee.

2.25 **"Award Agreement"** means the signed written agreement between the Company and a Grantee that sets out the terms and conditions of an Award.

2.26 **"Ordinance"** means the Israeli Income Tax Ordinance [New Version] 1961 as now in effect or as hereafter amended.

2.27 **"Purchase Price"** means the price for each Share subject to an Option**.**

2.28 **"Restricted Share"** means Shares subject to certain restrictions granted to a Grantee under the ISAP.

2.29 "**Restricted Period**" shall have the meaning ascribed to it in Section 5A.3 below.

2.30 **"Section 102"** means section 102 of the Ordinance as now in effect or as hereafter amended.

2.31 **"Share(s)"** means an ordinary share, NIS 1.00 par value, of the Company.

2.32 **"Successor Company"** means any entity the Company is merged to or is acquired by, in which the Company is not the surviving entity.

2.33 **"Transaction"** means (i) merger, acquisition or reorganization of the Company with one or more other entities in which the Company is not the surviving entity, or (ii) a sale of all or substantially all of the assets of the Company.

2.34 **"Trustee"** means any individual appointed by the Company to serve as a trustee and approved by the ITA, all in accordance with the provisions of Section 102(a) of the Ordinance.

2.35 **"Unapproved 102 Award"** means an Award granted pursuant to Section 102(c) of the Ordinance and not held in trust by a Trustee.

2.36 **"Vested Award"** means any Award, which has already been vested according to the Vesting Dates.

2.37 **"Vesting Dates"** means, as determined by the Board or by the Committee, the date as of which the Grantee shall be entitled to exercise the Options or part of the Options, as set forth in section 12 of the ISAP or the date on which the Restricted Period with respect to a Restricted Share shall elapse.

3. ADMINISTRATION OF THE ISAP

3.1 The Board shall have the power to administer the ISAP either directly or upon the recommendation of the Committee, all as provided by applicable law and in the Company's Articles of Association. Notwithstanding the above, the Board shall automatically have residual authority if no Committee shall be constituted or if such Committee does not exercise any of the powers granted to it hereunder or if such Committee shall cease to operate for any reason.

3.2 The Committee shall select one of its members as its Chairman and shall hold its meetings at such times and places as the Chairman shall determine. The Committee shall keep records of its meetings and shall make such rules and regulations for the conduct of its business as it shall deem advisable.

3.3 The Committee shall have the power to recommend to the Board and the Board shall have the full power and authority to: (i) designate participants; (ii) determine the terms and provisions of the respective Award Agreements, including, but not limited to, the type and number of Awards to be granted to each Grantee, including the number of Shares to be covered by each Option or the number of Restricted Shares to be covered by each Award of Restricted Shares, provisions concerning the time and the extent to which the Options may be exercised or concerning the Restricted Period and the nature and duration of restrictions as to the transferability or restrictions constituting substantial risk of forfeiture and to cancel or suspend awards, as necessary; (iii) determine the Fair Market Value of the Shares covered by each Award; (iv) make an election as to the type of Approved 102 Award; and (v) designate the type of Awards.

Subject to applicable law, the Committee shall have full power and authority to :(i) grant Awards to the Grantees and to issue Restricted Shares and Shares underlying Options duly exercised pursuant to the provisions herein, in accordance with section 288(b) of the Companies Law; (ii) alter any restrictions and conditions of any Options or Shares subject to any Awards (iii); interpret the provisions and supervise the administration of the ISAP; (iv) accelerate the right of a Grantee to exercise in whole or in part, any previously granted Option; (v) determine the Purchase Price of the Option; (vi) prescribe, amend and rescind rules and regulations relating to the ISAP; and (vii) make all other determinations deemed necessary or advisable for the administration of the ISAP, including, without limitation, to adjust the terms of the ISAP or any Award Agreement so as to reflect (a) changes in applicable laws and (b) the laws of other jurisdictions within which the Company wishes to grant Awards.

3.4 Notwithstanding the above, the Committee shall not be entitled to grant Awards to persons who are not Employees, however, it will be authorized to issue Shares underlying Options which have been granted by the Board and duly exercised pursuant to the provisions herein in accordance with section 112(a)(5) of the Companies Law.

3.5 The Board shall have the authority to grant, at its discretion, to the holder of an outstanding Option, whether or not such holder is an Employee, in exchange for the surrender and cancellation of such Option, a new Option having a purchase price equal to, lower than or higher than the Purchase Price of the original Option so surrendered and canceled and containing such other terms and conditions as the Committee may prescribe in accordance with the provisions of the ISAP. The Committee shall have the same authority solely with respect to holders of outstanding Options who are Employees.

3.6 3.6 Subject to the Company's Articles of Association, all decisions and selections made by the Board or the Committee pursuant to the provisions of the ISAP shall be made by a majority of its members except that no member of the Board or the Committee shall vote on, or be counted for quorum purposes, with respect to any proposed action of the Board or the Committee relating to any Award to be granted to that member, unless permitted under applicable law and in accordance therewith. Any decision reduced to writing shall be executed in accordance with the provisions of the Company's Articles of Association, as the same may be in effect from time to time.

3.7 The interpretation and construction by the Committee of any provision of the ISAP or of any Award Agreement thereunder shall be final and conclusive unless otherwise determined by the Board.

3.8 Subject to the Company's Articles of Association and the Company's decision, and to all approvals legally required, including, but not limited to the provisions of the Companies Law, each member of the Board or the Committee shall be indemnified and held harmless by the Company against any cost or expense (including counsel fees) reasonably incurred by him/her, or any liability (including any sum paid in settlement of a claim with the approval of the Company) arising out of any act or omission to act in connection with the ISAP, unless arising out of such member's own fraud or bad faith, to the extent permitted by applicable law. Such indemnification shall be in addition to any rights of indemnification the member may have as a director or otherwise under the Company's Articles of Association, any agreement, any vote of shareholders or disinterested directors, insurance policy or otherwise.

4. DESIGNATION OF PARTICIPANTS

4.1 The persons eligible for participation in the ISAP as Grantees shall include any Employees and/or Non-Employees of the Company or of any Affiliate; provided, however, that (i) Employees may only be granted 102 Awards; (ii) Non-Employees may only be granted 3 (i) Awards; and (iii) Controlling Shareholders may only be granted 3(i) Awards.

4.2 The grant of an Award hereunder shall neither entitle the Grantee to participate nor disqualify the Grantee from participating in, any other grant of Awards pursuant to the ISAP or any other option or share plan of the Company or any of its Affiliates.

4.3 Anything in the ISAP to the contrary notwithstanding, all grants of Awards to directors and office holders shall be authorized and implemented in accordance with the provisions of the Companies Law or any successor act or regulation, as in effect from time to time.

5. DESIGNATION OF AWARDS PURSUANT TO SECTION 102

5.1 The Company may designate Awards granted to Employees pursuant to Section 102 as Unapproved 102 Awards or Approved 102 Awards.

5.2 The grant of Approved 102 Awards shall be made under this ISAP adopted by the Board as described in Section 15 below, as may be amended by the Board from time to time, and shall be conditioned upon the approval of this ISAP by the ITA.

5.3 Approved 102 Awards may either be classified as an Capital Gain Award ("**CGA**") or Ordinary Income Award ("**OIA**").

5.4 Approved 102 Awards elected and designated by the Company to qualify under the capital gain tax treatment in accordance with the provisions of Section 102(b)(2) shall be referred to herein as "**CGA**".

5.5 Approved 102 Awards elected and designated by the Company to qualify under the ordinary income tax treatment in accordance with the provisions of Section 102(b)(1) shall be referred to herein as "**OIA**".

5.6 The Company's election of the type of Approved 102 Awards as CGA or OIA granted to Employees (the "**Election**"), shall be appropriately filed with the ITA before the Date of Grant of an Approved 102 Award. Such Election shall become effective beginning the first Date of Grant of an Approved 102 Award under this ISAP and shall remain in effect until the end of the year following the year during which the Company first granted Approved 102 Awards. The Election shall obligate the Company to grant *only* the type of Approved 102 Awards it has elected, and shall apply to all Grantees who were granted Approved 102 Awards during the period indicated herein, all in accordance with the provisions of Section 102(g) of the Ordinance. For the avoidance of doubt, such Election shall not prevent the Company from granting Unapproved 102 Awards or 3(i) Awards simultaneously.

5.7 All Approved 102 Awards must be held in trust by a Trustee, as described in Section 6 below.

5.8 For the avoidance of doubt, the designation of Unapproved 102 Awards and Approved 102 Awards shall be subject to the terms and conditions set forth in Section 102 of the Ordinance and the regulations promulgated thereunder, as may be amended from time to time.

5A RESTRICTED SHARES

5A.1 Award of Restricted Shares. Awards of Restricted Shares may be issued either alone or in addition to other Awards granted under the ISAP. Subject to the terms and conditions of the ISAP, the Board or the Committee, at any time and from time to time, may grant Awards of Restricted Shares to Grantees and may determine, at its sole discretion, the Grantees to whom, and the time or times at which, Awards of Restricted Shares will be made, the number of Restricted Shares to be awarded, the Restricted Period and all other conditions of the Awards of Restricted Shares.

5A2. Restricted Shares Award Agreement and Certificates. Each Award of Restricted Shares will be evidenced by an Award Agreement that will specify the number of Restricted Shares covered by the Award, the Restricted Period with respect to a Restricted Share and such other terms and conditions as the Board or the Committee, in its sole discretion, will determine. The Company may elect to cause Restricted Shares to be held through the Trustee until the restrictions on such Restricted Shares have lapsed.

5A3. Transferability. Except as provided in this Section 5A or the Award Agreement governing any such Award, Restricted Shares may not be sold, transferred, pledged, assigned, or otherwise alienated, hypothecated or disposed of, until the end of the applicable vesting period (the "**Restricted Period**").

5A4. Other Restrictions. The Board or the Committee, in its sole discretion, may impose such other restrictions on Restricted Shares as it may deem advisable or appropriate. The Board or the Committee may set restrictions based upon continued employment or service, the achievement of specific performance objectives (Company-wide, departmental, divisional, business unit, or individual), applicable federal or state securities laws, or any other basis determined by the Board or the Committee, in its discretion.

5A5. Removal of Restrictions. Except as otherwise provided in this Section 5A, Restricted Shares awarded under the ISAP will be released from trust (or from other applicable restrictions hereunder) as soon as practicable after the last day of the Restriction Period or at such other time as the Board or the Committee may determine. The Committee may, in its discretion, reduce or waive any vesting criteria and may accelerate the time at which any restrictions will lapse or be removed. The Board or the Committee, in its discretion, may establish procedures regarding the release of Restricted Shares from trust, as necessary or appropriate to minimize administrative burdens on the Company.

5A6. Voting Rights. Once the Grantee has been issued a certificate or certificates for Restricted Shares or the Restricted Shares have been issued in the Grantee's name by book-entry registration, during the Restricted Period, Grantees holding Restricted Shares granted hereunder may exercise full voting rights (either directly or by way of pass- through voting arrangements with the Trustee holding the Restricted Shares) with respect to those Restricted Shares, unless the Committee determines otherwise.

5A7. Dividends and Other Distributions. During the Restricted Period dividends and other distributions shall be payable with respect to Restricted Shares (either directly or by way of pass-through arrangements with the Trustee holding the Restricted Shares), unless the Board or the Committee determines otherwise and subject to applicable law, provided that any such dividends and other distributions shall only be paid or distributed to the Grantee at the end of the Restriction Period and a Grantee shall not be entitled to interest with respect to any such dividends or distributions subjected to the Restricted Period. During the Restricted Period, any such dividends or distributions shall be subject to the same restrictions on transferability and forfeitability as the Restricted Shares, with respect to which they were paid, unless otherwise provided in the Award Agreement. Unless otherwise determined by the Board or the Committee at any time subject to applicable law, any distributions or dividends paid in the form of securities with respect to Restricted Shares will be subject to the same terms and conditions as the Restricted Shares with respect to which they were paid, including, without limitation, the same Restriction Period.

5A8. Forfeiture of Restricted Shares. On the date set forth in the Award Agreement or in any termination event specified in such Award Agreement, the Restricted Shares, for which restrictions, including the Restriction Period, have not lapsed at such time, and any associated dividends, if any, that then remain subject to forfeiture will then be forfeited automatically and will become available for grant under the ISAP. Upon forfeiture of Restricted Shares, the Grantee shall have no further rights with respect to such Restricted Shares

5A9. 102 Award of Restricted Shares. In the event that Awards of Restricted Shares to Employees are designated as 102 Awards, such Awards of Restricted Shares shall be subject to Section 102 of the Ordnance and the provisions set forth in this ISAP relating to 102 Awards.

6. 3(i) AWARDS

6.1 Awards granted pursuant to this Section are intended to constitute 3(i) Awards and are subject to the provisions of Section 3(i) of the Ordinance and the general terms and conditions specified in the ISAP, except for provisions of the ISAP applying to Options granted under a different tax law or regulations.

6.2 3(i) Awards may be granted only to Non-Employees.

6.3 3(i) Awards that shall be granted pursuant to the ISAP may be issued directly to the Non- Employee or to a Trustee. In the event that the Board or the Committee determines that 3(i) Awards or Shares issued upon the exercise Options that are 3(i) Awards shall be deposited with a Trustee, the provisions of Section 7 hereof shall apply, mutatis mutandis.

7. TRUSTEE

7.1 Approved 102 Awards which shall be granted under the ISAP and/or any Shares allocated or issued upon exercise of such Approved 102 Awards and/or other shares received subsequently following any realization of rights, including without limitation bonus shares, shall be allocated or issued to the Trustee and held for the benefit of the Grantees for such period of time as required by Section 102 or any regulations, rules or orders or procedures promulgated thereunder (the "**Holding Period**"). In the case the requirements for Approved 102 Options are not met, then the Approved 102 Awards may be treated as Unapproved 102 Awards, all in accordance with the provisions of Section 102 and regulations promulgated thereunder.

7.2 Notwithstanding anything to the contrary, the Trustee shall not release any Approved 102 Award and/or Shares allocated or issued upon exercise of Approved 102 Awards prior to the full payment of the Grantee's tax liabilities arising from Approved 102 Awards, which were granted to him/her.

7.3 With respect to any Approved 102 Awards, subject to the provisions of Section 102 and any rules or regulation or orders or procedures promulgated thereunder, a Grantee shall not sell or release from trust any Approved 102 Award or any Share received upon the exercise of an Approved 102 Award and/or any share received subsequently following any realization of rights, including without limitation, bonus shares, until the lapse of the Holding Period required under Section 102 of the Ordinance. Notwithstanding the above, if any such sale or release occurs during the Holding Period, the sanctions under Section 102 of the Ordinance and under any rules or regulation or orders or procedures promulgated thereunder shall apply to and shall be borne by such Grantee.

7.4 Upon receipt of Approved 102 Award and if required by the Company and/or the Trustee, the Grantee will sign an undertaking to release the Trustee from any liability in respect of any action or decision duly taken and bona fide executed in relation with the ISAP, or any Approved 102 Award or Share granted to him/her thereunder, except in the event of negligence or willful misconduct on part of the Trustee.

8. SHARES RESERVED FOR THE ISAP; RESTRICTION THEREON

8.1 The Company has initially reserved 900,000 (nine hundred thousand) authorized but unissued Shares, for the purposes of the ISAP and for the purposes of any other share- based compensation plans which may be adopted by the Company in the future, subject to adjustment as set forth in Section 10 below or any increase in such amount of reserved Shares, as may be determined by the Board according to the terms hereof and subject to applicable law. Any Shares which remain unissued and which are not subject to the outstanding Awards at the termination of the ISAP shall cease to be reserved for the purpose of the ISAP, but until termination of the ISAP the Company shall, at all times reserve sufficient number of Shares to meet the requirements of the ISAP. Should any Award, for any reason expire, terminate or be canceled or forfeited prior to its exercise or relinquishment in full, or prior to the lapse of its restrictions according to the applicable Award Agreement, the Shares subject to such Award may, subject to applicable law, again be subjected to an Award under the ISAP or under the Company's other share- based compensation plans.

8.2 Each Award granted pursuant to the ISAP, shall be evidenced by a written Award Agreement between the Company and the Grantee, in such form as the Board or the Committee shall from time to time approve. Each Award Agreement shall state, among other matters, the type and number of Awards granted, the type of Award granted thereunder (e.g., CGA, OIA, Unapproved 102 Award or a 3(i) Award, etc.), the Vesting Dates, the Purchase Price for Shares subject to an Option, the Expiration Date and such other terms and conditions as the Committee or the Board in its discretion may prescribe, provided that they are consistent with this ISAP and applicable law.

9. PURCHASE PRICE OF OPTIONS

9.1 The Purchase Price of each Share subject to Options shall be determined by the Committee in its sole and absolute discretion in accordance with applicable law, subject to any guidelines as may be determined by the Board from time to time. Each Award Agreement will contain the Purchase Price determined for each Grantee of Options.

9.2 The Purchase Price for Shares subject to an Option shall be payable upon the exercise of an Option in a form satisfactory to the Committee, including without limitation, by cash or check. The Committee shall have the authority to postpone the date of payment on such terms as it may determine. Notwithstanding the foregoing, the Board may determine that the exercise of any Option(s) granted under this ISAP shall be made according to a method of exercise known as "cashless exercise", according to which method the Grantee is not required to pay the Purchase Price when exercising the Options, but simply receives such number of Shares, which total Fair Market Value equal to the total net amount of the increase in the Fair Market Value of the Shares covered under such Options Award above the Purchase Price, in Shares, according to a formula to be determined by the Board. In such event the Board, at its sole discretion and subject to applicable law, may exempt the Grantee from the payment of the par value of the Shares actually issued to him/her as a result of such exercise of Options.

9.3 The Purchase Price shall be denominated in the currency of the primary economic environment of, either the Company or the Grantee (that is the functional currency of the Company or the currency in which the Grantee is paid) as determined by the Company.

10. ADJUSTMENTS

Upon the occurrence of any of the following described events, Awards granted under the ISAP shall be adjusted as hereafter provided:

10.1 Without derogating from the Board or the Committee's general authority and power under this ISAP, in the event of a Transaction the Board or the Committee may take any one or more of the following actions with respect to the then outstanding Awards, without the Grantees' consent and action and without any prior notice requirement: (i) provide for the assumption or substitution of any Award for an appropriate number of shares or other securities of the Successor Company (or a parent or subsidiary of the Successor Company), under such terms and conditions as determined by the Board or the Committee; (ii) provide for the acceleration of vesting of such Award, as to all or part of those portions of the Award which would not otherwise be exercisable or vested, under such terms and conditions as the Board or the Committee shall determine in their sole and absolute discretion; (iii) provide for the cancellation of any Award without any consideration, if the Fair Market Value per Share on the date of the Transaction does not exceed the Purchase Price of any such Award or if such Award would not otherwise be exercisable or vested, even in the event that the Fair Market Value per Share on the date of the Transaction, exceeds the Purchase Price of any such Award.

10.2 Notwithstanding the above and subject to any applicable law, the Board or the Committee shall have full power and authority to determine that in certain Award Agreements there shall be a clause instructing that, if in any such Transaction as described in section 9.1 above, the Successor Company (or parent or subsidiary of the Successor Company) does not agree to assume or substitute the Awards, the Vesting Dates shall be accelerated so that any unvested Award or any portion thereof shall be immediately vested as of the date which is ten (10) days prior to the effective date of the Transaction.

10.3 For the purposes of section 10.1(i) above, an Award shall be considered assumed or substituted if, following the Transaction, the Awards confers the right to purchase or receive, for each Share underlying an Award immediately prior to the Transaction, the consideration (whether shares, options, cash, or other securities or property) received in the Transaction by holders of Shares held on the effective date of the Transaction (and if such holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares); provided, however, that if such consideration received in the Transaction is not solely ordinary shares (or their equivalent) of the Successor Company or its parent or subsidiary, the Committee may, with the consent of the Successor Company, provide for the consideration to be received upon the exercise of an Option subject to an Award to be solely ordinary shares (or their equivalent) of the Successor Company or its parent or subsidiary equal in Fair Market Value to the per Share consideration received by holders of a majority of the outstanding Shares in the Transaction; and provided further that the Committee may determine, in its discretion, that in lieu of such assumption or substitution of Options for options of the Successor Company or its parent or subsidiary, such Options will be substituted for any other type of asset or property including cash which is fair under the circumstances.

10.4 If the Company is voluntarily liquidated or dissolved (i) while unexercised Options subject to an Award remain outstanding under the ISAP, the Company shall immediately notify all unexercised Option holders of such liquidation, and the Option holders shall then have ten (10) days to exercise any unexercised Vested Option held by them at that time, in accordance with the exercise procedure set forth herein. Upon the expiration of such ten- days period, all remaining outstanding Options will terminate immediately; and (ii) all Restricted Shares subject to an Award, for which restrictions, including the Restriction Period, have not lapsed at such time, and any associated dividends (if any) that then remain subject to forfeiture will then be forfeited automatically prior to the consummation of such liquidation or dissolution.

10.5 If the outstanding Shares of the Company shall at any time be changed or exchanged by declaration of a share dividend (bonus shares), share split, combination or exchange of shares, recapitalization, or any other like event by or of the Company, and as often as the same shall occur, then the number, class and kind of the Shares subject to the ISAP or subject to any Awards therefore granted, and the Purchase Prices of Options, shall be appropriately and equitably adjusted so as to maintain the proportionate number of Shares without changing the aggregate Purchase Price of Options, provided, however, that no adjustment shall be made by reason of the distribution of subscription rights (rights offering) on outstanding Shares. Without derogating from the foregoing, upon happening of any of the foregoing, the class and aggregate number of Shares issuable pursuant to the ISAP (as set forth in Section 8 hereof), in respect of which Options subject to Awards have not yet been exercised, shall be appropriately adjusted, all as will be determined by the Board whose determination shall be final.

10.6 The Grantee acknowledges that in the event that the Shares shall be registered for trading in any public market, Grantee's rights to sell the Shares may be subject to certain limitations (including a lock-up period), as will be requested by the Company or its underwriters, and the Grantee unconditionally agrees and accepts any such limitations.

11. TERM AND EXERCISE OF OPTIONS

11.1 Options shall be exercised by the Grantee by giving written notice to the Company and/or to any third party designated by the Company (the "**Representative**"), in such form and method as may be determined by the Company and when applicable, by the Trustee in accordance with the requirements of Section 102, which exercise shall be effective upon receipt of such notice by the Company and/or the Representative and the payment of the Purchase Price, or, in the event of cashless exercise (as described in Section 9.2 above), the surrender of portion of the Shares, at the Company's or the Representative's principal office. The notice shall specify the number of Options being exercised.

11.2 Options, to the extent not previously exercised, shall expire forthwith upon the earlier of: (i) the date set forth in the Award Agreement; and (ii) the expiration of any extended period in any of the events set forth in section 11.5 below.

11.3 The Options may be exercised by the Grantee in whole at any time or in part from time to time, to the extent that the Options become vested and exercisable, prior to the Expiration Date, and provided that, subject to the provisions of section 11.5 below, the Grantee is employed by or providing services (including directorship services) to the Company or any of its Affiliates, at all times during the period beginning on the Date of Grant and ending upon the later of: (a) the date of exercise; or (b) the applicable term specified in section 11.5 below.

Subject to the provisions of section 11.5 below, in the event of termination of Grantee's employment or services, with the Company or any of its Affiliates, all Options granted to such Grantee will immediately expire. A notice of termination of employment or service shall be deemed to constitute termination of employment or service. For the avoidance of doubt, in case of such termination of employment or service, the unvested portion of the Grantee's Options shall not vest and shall not become exercisable. For the sake of clarification and avoidance of doubt, the transition from an Employee of the Company and/or its Affiliates to a Non-Employee who is a consultant, adviser or service provider of the Company and/or its Affiliates prior to the Expiration Date (or vice versa) shall not be deemed to constitute termination of the Grantee's employment or service with the Company or any of its Affiliates for purposes of this ISAP and the Award Agreement, such that in such case, the Grantee's Options shall continue to vest and become exercisable according to the applicable Vesting Dates, provided that the Grantee is employed by or providing services (including directorship services) to the Company or any of its Affiliates at all times until the applicable Vesting Dates.

11.4 Notwithstanding anything to the contrary hereinabove and unless otherwise determined in the Grantee's Award Agreement, an Option may be exercised after the date of termination of Grantee's employment or service with the Company or any Affiliates during an additional period of time beyond the date of such termination, but only with respect to the number of Vested Options at the time of such termination according to the Vesting Dates, if**:**

(i) termination is due to Grantee's resignation, other than in the circumstances described in paragraph (iii) below, in which event any Vested Option still in force and unexpired may be exercised within a period of ninety (90) days after the effective date of such termination, provided that to the extent that upon termination of such ninety (90) days' period there is a lasting blackout period preventing the Grantee from exercising his/her Options, the Company's CEO or CFO may extend such ninety (90) days' period for additional limited periods until the lapse of such blackout period; or-

(ii) termination is initiated by the Company without Cause, in which event any Vested Award still in force and unexpired may be exercised within a period of ninety (90) days after the effective date of such termination; or-

(iii) termination is due to Grantee's retirement, in which event any Vested Award still in force and unexpired may be exercised within a period of ninety (90) days after the effective date of such termination; or-

(iv) termination is the result of death or disability of the Grantee, in which event any Vested Award still in force and unexpired may be exercised within a period of twelve (12) months after the effective date of such termination; or –

(v) prior to the date of such termination, the Committee shall authorize an extension of the terms of all or part of the Vested Awards beyond the date of such termination for a period not to exceed the period during which the Options by their terms would otherwise have been exercisable.

For avoidance of any doubt, if termination of employment or service is for Cause, any outstanding unexercised Option (whether vested or non-vested), will immediately expire and terminate, and the Grantee shall not have any right in connection to such outstanding Options.

11.5 To avoid doubt, the Grantees shall not have any of the rights or privileges of shareholders of the Company in respect of any Shares purchasable upon the exercise of any Option, nor shall they be deemed to be a class of shareholders or creditors of the Company for purpose of the operation of sections 350 and 351 of the Companies Law or any successor to such section, until registration of the Grantee as holder of such Shares in the Company's register of shareholders upon exercise of the Option in accordance with the provisions of the ISAP, but in case of Options and Shares held by the Trustee, subject to the provisions of Section 6 of the ISAP.

11.6 Any form of Award Agreement may contain such other provisions as the Committee may, from time to time, deem advisable.

11.7 With respect to Unapproved 102 Awards that are Options, if the Grantee ceases to be employed by the Company or any Affiliate, the Grantee shall extend to the Company and/or its Affiliate a security or guarantee for the payment of tax due at the time of sale of Shares, all in accordance with the provisions of Section 102 and the rules, regulation or orders promulgated thereunder.

12. VESTING OF OPTIONS

12.1 Subject to the provisions of the ISAP, each Option subject to an Award shall vest following the Vesting Dates and for the number of Shares as shall be provided in the Award Agreement. However, no Option shall be exercisable after the Expiration Date.

12.2 An Option may be subject to such other terms and conditions on the time or times when it may be exercised, as the Committee may deem appropriate. The vesting provisions of individual Options may vary.

13. NO RIGHT OF FIRST REFUSAL

Notwithstanding anything to the contrary in the Articles of Association of the Company, none of the Grantees shall have a right of first refusal in relation with any sale of Shares in the Company.

14. DIVIDENDS

Subject to the provisions of Section 5A.7 with respect to Restricted Shares, with respect to all Shares issued under the ISAP (but excluding, for avoidance of any doubt, any unexercised Options), the Grantee shall be entitled to receive dividends in accordance with the quantity of such Shares, subject to applicable law and the provisions of the Company's Articles of Association (and all amendments thereto) and subject to any applicable taxation on distribution of dividends, and when applicable subject to the provisions of Section 102 and the rules, regulations or orders promulgated thereunder.

15. RESTRICTIONS ON ASSIGNABILITY AND SALE OF OPTIONS

15.1 No Option or any right with respect thereto, purchasable hereunder, whether fully paid or not, shall be assignable, transferable or given as collateral or any right with respect to it given to any third party whatsoever, except as specifically allowed under the ISAP, and during the lifetime of the Grantee each and all of such Grantee's rights to purchase Shares hereunder shall be exercisable only by the Grantee.

Any such action made directly or indirectly, for an immediate validation or for a future one, shall be void.

15.2 As long as the Shares are held by the Trustee on behalf of the Grantee, all rights of the Grantee over the Shares are personal, cannot be transferred, assigned, pledged or mortgaged, other than by will or pursuant to the laws of descent and distribution.

16. EFFECTIVE DATE AND DURATION OF THE ISAP

The ISAP shall be effective as of the day it was adopted by the Board and shall terminate on August 9, 2031[1].

The Company shall obtain the approval of the Company's shareholders for the adoption of this ISAP or for any amendment to this ISAP, if shareholders' approval is necessary or desirable to comply with any applicable law including without limitation the US securities law or the securities laws of other jurisdiction applicable to Awards granted to Grantees under this ISAP, or if shareholders' approval is required by any authority or by any governmental agencies or national securities exchanges including, without limitation, the US Securities and Exchange Commission.

17. AMENDMENTS OR TERMINATION

The Board may at any time, and when applicable after consultation with the Trustee, amend, alter, suspend or terminate the ISAP. No amendment, alteration, suspension or termination of the ISAP shall impair the rights of any Grantee, unless mutually agreed otherwise between the Grantee and the Company, which agreement must be in writing and signed by the Grantee and the Company. Termination of the ISAP shall not affect the Committee's ability to exercise the powers granted to it hereunder with respect to Awards granted under the ISAP prior to the date of such termination.

18. GOVERNMENT REGULATIONS

The ISAP, and the granting and exercise of Awards hereunder, and the obligation of the Company to sell and deliver Shares under Options subject to Awards, shall be subject to all applicable laws, rules, and regulations, whether of the State of Israel or of the United States or any other State having jurisdiction over the Company and the Grantee, including the registration of the Shares under the United States Securities Act of 1933, and the Ordinance and to such approvals by any governmental agencies or national securities exchanges as may be required. Nothing herein shall be deemed to require the Company to register the Shares under the securities laws of any jurisdiction.

19. CONTINUANCE OF EMPLOYMENT OR HIRED SERVICES

Neither the ISAP nor the Award Agreement with the Grantee shall impose any obligation on the Company or an Affiliate thereof, to continue any Grantee in its employ or service, and nothing in the ISAP or in any Award granted pursuant thereto shall confer upon any Grantee any right to continue in the employ or service of the Company or an Affiliate thereof or restrict the right of the Company or an Affiliate thereof to terminate such employment or service at any time.

20. GOVERNING LAW & JURISDICTION

The ISAP shall be governed by and construed and enforced in accordance with the laws of the State of Israel applicable to contracts made and to be performed therein, without giving effect to the principles of conflict of laws. The competent courts of Tel-Aviv, Israel shall have sole jurisdiction in any matters pertaining to the ISAP.

[1] In order to comply with ISO requirements, this date should not be more than 10 years from the date of the board resolution approving the plan.

21. TAX CONSEQUENCES

21.1 Any tax consequences arising from the grant or exercise of any Award, from the payment for Shares covered thereby or from any other event or act (of the Company and/or its Affiliates, the Trustee or the Grantee), hereunder, shall be borne solely by the Grantee. The Company and/or its Affiliates and/or the Trustee shall withhold taxes according to the requirements under the applicable laws, rules, and regulations, including withholding taxes at source. Furthermore, the Grantee shall agree to indemnify the Company and/or its Affiliates and/or the Trustee and hold them harmless against and from any and all liability for any such tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax from any payment made to the Grantee.

21.2 The Company and/or, when applicable, the Trustee shall not be required to release any Share certificate to a Grantee until all required payments have been fully made.

22. NON-EXCLUSIVITY OF THE ISAP

The adoption of the ISAP by the Board shall not be construed as amending, modifying or rescinding any previously approved incentive arrangements or as creating any limitations on the power of the Board to adopt such other incentive arrangements as it may deem desirable, including, without limitation, the granting of Awards otherwise than under the ISAP, and such arrangements may be either applicable generally or only in specific cases.

For the avoidance of doubt, prior grant of Awards to Grantees of the Company under their employment agreements, and not in the framework of any previous option plan, shall not be deemed an approved incentive arrangement for the purpose of this Section.

23. MULTIPLE AGREEMENTS

The terms of each Award may differ from other Awards granted under the ISAP at the same time, or at any other time. The Board may also grant more than one Award to a given Grantee during the term of the ISAP, either in addition to, or in substitution for, one or more Awards previously granted to that Grantee.

KAMADA LTD.
2011 ISRAEL SHARE AWARD PLAN

APPENDIX – U.S. TAXPAYERS

1. Special Provisions for Persons who are U.S. Taxpayers.

1.1 This Appendix – U.S. Taxpayers (this "**Appendix**") to the Kamada Ltd. 2011 Israel Share Award Plan (the "**ISAP**") was approved by the Board of Directors of Kamada Ltd. (the "**Board**") on February 28, 2022 (the "**Effective Date**"). Subject to Section 1.4 hereof and Section 2 of this Appendix, capitalized terms not otherwise defined herein shall have the meaning assigned to them in the ISAP.

1.2 The provisions of this Appendix apply only to persons who are subject to U.S. federal income tax (any such person, a "**U.S. Taxpayer**"). This Appendix provides for the grant of Options and Restricted Shares. Options granted under this Appendix may include Incentive Stock Options intended to qualify under Section 422 of the Code as well as Non-Qualified Stock Options.

1.3 Except as otherwise provided by this Appendix, all grants made pursuant to this Appendix shall be governed by the terms of the ISAP (including, without limitation, its provisions regarding adjustments). This Appendix is applicable to all Awards granted to U.S. Taxpayers under the ISAP.

1.4 The Plan and this Appendix shall be read together. In any case of an irreconcilable contradiction (as determined by the Board) between the provisions of this Appendix and the ISAP, the provisions of this Appendix shall govern unless expressly stated otherwise in the ISAP. For purposes of clarification, if any term is defined in the ISAP and this Appendix differently, then the term (as used in this Appendix and any Award Agreement issued in connection with this Appendix) shall have the meaning as defined in this Appendix.

1.5 This Appendix shall be submitted to the Company's shareholders for approval within twelve (12) months after the Effective Date. As of the Effective Date, the Board may grant Awards pursuant to this Appendix; provided, however, that: (a) no Incentive Stock Option may be exercised under this Appendix prior to initial shareholder approval of the ISAP and this Appendix; (b) if such approval has not been obtained at the end of said twelve-month period, all Incentive Stock Options previously granted or awarded under the ISAP and this Appendix shall thereupon be automatically converted into and treated as Non-Qualified Stock Options; and (c) no Incentive Stock Option granted pursuant to an increase in the number of Shares approved by the Board shall be exercised prior to the time such increase has been approved by the shareholders of the Company.

2. Definitions.

Capitalized terms not otherwise defined herein shall have the meaning assigned to them in the ISAP. The following additional definitions will apply to grants made pursuant to this Appendix:

"Affiliate" means each of the following: (a) any Subsidiary; (b) any Parent; (c) any corporation, trade or business (including, without limitation, a partnership or limited liability company) that is directly or indirectly controlled 50% or more (whether by ownership of stock, assets or an equivalent ownership interest or voting interest) by the Company or one of its Subsidiaries or Parents, if any; and (d) any other entity in which the Company or any of its Affiliates has a material equity interest and that is designated as an "Affiliate" by resolution of the Board provided, however, that if an individual who otherwise qualifies as a Service Provider provides services to such an entity and not to the Company or a Subsidiary or Parent, such entity may only be designated an Affiliate if the Company qualifies as a "service recipient," within the meaning of Code Section 409A, with respect to such individual

"Code" means the U.S. Internal Revenue Code of 1986, as amended. Any reference to any section of the Code shall also be a reference to any successor provision and any Treasury Regulation promulgated thereunder.

"**Disability**" means, with respect to Incentive Stock Options, a "permanent and total disability" within the meaning of Code Section 22(e)(3), provided that in the case of Awards other than Incentive Stock Options, the Board in its discretion may determine whether a Disability exists in accordance with the ISAP. Notwithstanding the foregoing, for Awards subject to Code Section 409A, Disability shall mean that a Grantee is disabled under Code Section 409A(a)(2)(C).

"**Employee**" means any person, including an officer or Director, employed by the Company or an Affiliate.

"**Fair Market Value**" means, for purposes of this Appendix, unless otherwise required by any applicable provision of the Code or any regulations issued thereunder, as of any date and except as provided below, (a) if the Shares are listed on any established securities exchange, the closing sales price for such Shares (or the closing bid, if no sales were reported) as traded on such exchange for such date, or if no bids or sales were reported for such date, then the closing sales price (or the closing bid, if no sales were reported) on the trading date immediately prior to such date during which a bid or sale occurred, in each case, as reported in a recognized daily business newspaper or such other source as the Board deems reliable; or (b) in the absence of an established market for the Shares, the Fair Market Value shall be determined in good faith by the Board, taking into account such factors as it considers advisable in a manner consistent with the principles of Code Section 409A or, with respect to Incentive Stock Options, Code Section 422.

"Grantee" means a Service Provider who receives an Award hereunder.

"**Incentive Stock Option**" means any Option awarded under the ISAP and this Appendix to an Eligible Recipient who is an employee of the Company, a Parent or any Subsidiary intended to be and designated in the Award Agreement as an "incentive stock option" within the meaning of Code Section 422.

"**Non-Qualified Stock Option**" shall mean an Option not described in Section 422(b) or 423(b) of the Code, or, which, by its terms, does not qualify or is not intended to qualify as an Incentive Stock Option.

"**Parent**" means any parent corporation of the Company within the meaning of Section 424(e) of the Code.

"Section 83(b) Election" means an election by a Grantee to include the Fair Market Value of a Share (less any amount paid for the Share) at the time of grant as part of the Participant's income in accordance with Section 83(b) of the Code. A Section 83(b) Election must be filed in writing with the Internal Revenue Service within thirty (30) days of the date of the Award, with a copy to the Company or Affiliate with whom the Grantee is employed.

"**Service Provider**" means an Employee or Non-Employee of the Company or any Affiliate.

"**Subsidiary**" means any subsidiary corporation of the Company within the meaning of Section 424(f) of the Code.

"**Ten Percent Shareholder**" means a person possessing more than 10% of the total combined voting power of all classes of shares of the Company, its Subsidiaries or its Parent determined pursuant to the attribution rules set forth in Section 424(d) of the Code.

3. Shares Reserved under Appendix for Incentive Stock Options.

Subject to adjustment upon changes in capitalization as provided in Section 10.5 of the ISAP and to the extent allowable under Code Section 422, the aggregate maximum number of Shares that may be issued upon the exercise of Incentive Stock Options under the ISAP is 500,000. Such maximum number of Shares that may be issued upon the exercise of Incentive Stock Options shall not be increased without the approval of the shareholders of the Company as required pursuant to Code Section 422.

4. Terms and Conditions of Awards or Sales.

4.1 *Award Agreement* (a). Each Award shall be evidenced by an Award Agreement between the Grantee and the Company and shall be subject to all applicable terms and conditions of the ISAP and this Appendix and may be subject to any other terms and conditions which are not inconsistent with the ISAP and this Appendix and which the Board deems appropriate for inclusion in an Award Agreement. The provisions of the various Award Agreements entered into under the Appendix need not be identical.

4.2 *Withholding Taxes* (a). As a condition to the grant of an Award or the purchase or acquisition of any Shares hereunder, the Grantee shall make such arrangements as the Board may require for the satisfaction of any federal, state, local or foreign withholding tax obligations that may arise in connection with such Award or purchase or acquisition of Shares, including, by way of example and not limitation, upon the grant or vesting of an Award, purchase or acquisition of Shares or upon Grantee making a Section 83(b) Election.

4.3 *Restrictions on Transfer of Awards***.** No Award shall be assigned, transferred or otherwise disposed of by any Grantee otherwise than by will or by the laws of descent and distribution, and all Options shall be exercisable, during the Grantee's lifetime, only by the Grantee or Grantee's legal representative.

4.4 *Restrictions on Transfer of Shares***.** Any Shares awarded or sold under the ISAP and this Appendix may be subject to such special forfeiture conditions, rights of repurchase, rights of first refusal and other transfer restrictions as the Board may determine. Such restrictions shall be set forth in the applicable Award Agreement and shall *apply* in addition to any restrictions that may apply to holders of Shares generally, and subject to the requirements of applicable law.

5. Grants of Options.

5.1 *Generally*. The Board shall have full authority to grant Options to Service Providers pursuant to the terms of this Appendix, the ISAP and the applicable Award Agreement. All Options shall be granted by, confirmed by, and subject to the terms of, an Award Agreement to be executed by the Company and the Grantee. In particular, the Board shall have the authority to determine whether an Option is intended to qualify as an Incentive Stock Option or is a Non-Qualified Stock Option.

5.2 *Eligibility*. All Service Providers are eligible to be granted Non-Qualified Stock Options under this Appendix, and only Employees of the Company, a Subsidiary or a Parent are eligible to be granted Incentive Stock Options under the ISAP and this Appendix, if so employed on the grant date of such Incentive Stock Option. Eligibility for the grant of an Option and actual participation in this Appendix and the ISAP shall be determined by the Board in its sole discretion.

5.3 *Purchase Price*. Each Award Agreement shall state the purchase price per share of the Shares covered by each Option, which option price shall be determined by the Board and shall be at least equal to the Fair Market Value per Share on the date of grant of the Option; provided that if the purchase price of an Option is less than Fair Market Value, the terms of such Option shall be structured in a manner that is intended to comply with the requirements of Section 409A of the Code. In addition, the terms of Section 6 shall apply to the grant of Incentive Stock Options.

6. Special Terms for Incentive Stock Options.

6.1 *Disqualification*. To the extent that any Option does not qualify as an Incentive Stock Option (whether because of its provisions or the time or manner of its exercise or otherwise), such Option or the portion thereof that does not qualify shall constitute a separate Non-Qualified Stock Option.

6.2 *Purchase Price*. The purchase price per Share subject to an Incentive Stock Option shall be determined by the Board at the time of grant of such Incentive Stock Option; provided that the per share purchase price of an Incentive Stock Option shall not be less than 100% of the Fair Market Value of the Share at the time of grant of such Incentive Stock Option; and provided, further, that if an Incentive Stock Option is granted to a Ten Percent Shareholder, the purchase price per Share shall be no less than 110% of the Fair Market Value of the Share at the time of the grant of such Incentive Stock Option.

6.3 *Option Term*. The term of each Incentive Stock Option shall be fixed by the Board; provided, however, that no Incentive Stock Option shall be exercisable more than 10 years after the date such Incentive Stock Option is granted; and further provided that the term of an Incentive Stock Option granted to a Ten Percent Shareholder shall not exceed five years. Unless otherwise determined by the Board, any extension of the term of an Option shall comply with Code Section 409A.

6.4 *Incentive Stock Option Limitations*. To the extent that the aggregate Fair Market Value (determined as of the time of grant) of Shares with respect to which Incentive Stock Options are exercisable for the first time by an employee during any calendar year under this Plan and/or any other stock option plan of the Company, any Subsidiary or any Parent exceeds US$100,000, such Incentive Stock Options shall be treated as Non-Qualified Stock Options. For purposes of this Section 6.4 Incentive Stock Options will be taken into account in the order in which they were granted, the Fair Market Value of the Shares will be determined as of the time the Option with respect to such Shares is granted, and calculation will be performed in accordance with Code Section 422 and Treasury Regulations promulgated thereunder. Should any provision of this Appendix not be necessary in order for the Options to qualify as Incentive Stock Options, or should any additional provisions be required, the Board may amend this Appendix accordingly, without the necessity of obtaining the approval of the shareholders of the Company, unless required by applicable law.

6.5 *Effect of Termination*. If a Grantee does not remain employed by the Company, any Subsidiary or any Parent at all times from the time an Incentive Stock Option is granted until three months prior to the date of exercise thereof (or such other period as required by Section 422 of the Code), such Incentive Stock Option shall be treated as a Non-Qualified Stock Option. Notwithstanding anything to the contrary in the ISAP or this Appendix, and in the absence of a provision specifying otherwise in the relevant Award Agreement, then with respect to Incentive Stock Options, the following provisions must be met in order for the Award to qualify as an Incentive Stock Option under the Code:

(a) In the event that the Grantee ceases to be an employee of the Company or any Subsidiary or Parent for any reason other than the Grantee's death or Disability, the vested Options must be exercised within three (3) months from the effective date of termination of the Grantee's employment with the Company or any Subsidiary or Parent.

(b) In the event that the Grantee's employment with the Company, a Subsidiary or Parent terminates as a result of the Grantee's Disability, the Option must be exercised within twelve (12) months following the Grantee's Date of Termination for Disability.

To avoid doubt, the provisions of Section 11.5 of the ISAP shall remain in full force and effect and apply to Options granted as Incentive Stock Options. The restrictions set forth above represent special additional limitations that apply to qualify as Incentive Stock Options under the provisions of the Code. To avoid doubt, to the extent different than the terms under this section 6.5, a Grantee may choose to exercise Options in accordance with the terms of Section 11.5 of the ISAP and the relevant Award Agreement, and not in compliance with the provisions of the Code relating to "incentive stock options". In that case such Option will not qualify as an Incentive Stock Option and will be treated as a Non-Qualified Stock Option.

6.6 *Notice of Disposition*. The Grantee shall give the Company prompt notice of any disposition of Shares acquired by exercise of an Incentive Stock Option within (i) two years from the date of grant of such Incentive Stock Option or (ii) one year after the transfer of such Shares to the Grantee.

6.7 *Right to Exercise*. During a Grantee's lifetime, an Incentive Stock Option may be exercised only by the Grantee.

6.8 *Incentive Stock Option Status*. Subject to the provisions herof, each Award designated as an Incentive Stock Option is intended to qualify as an Incentive Stock Option and any ambiguities or ambiguous terms herein will be construed and interpreted in accordance with such intent. In no event whatsoever shall the Company be liable for any additional tax, interest or penalties that may be imposed on the Grantee by reason of an Award not qualifying as an Incentive Stock Option or for any damages for failing to comply with qualifying as an Incentive Stock Option under the Code. Should any provision of this Appendix not be necessary in order for the Options to qualify as Incentive Stock Options, or should any additional provisions be required, the Board may, but is under no obligation to, amend this Appendix accordingly, without the necessity of obtaining the approval of the shareholders of the Company, unless required by applicable law.

7. <u>Restricted Shares and Share-Based Awards</u>.

7.1 *Restricted Shares.* A grant of Shares of Restricted Shares as provided for in the ISAP may, but is not required to, have a purchase price which may be set at the discretion of the Board or the Board as applicable. In the case of a grant of Shares of Restricted Shares for which a purchase price is required, such grant shall not be made until arrangements for payment of the purchase price have been established that are satisfactory to the Board.

7.2 *Section 83(b) Election*. If a Grantee makes a Section 83(b) Election to be taxed with respect to an Award as of the date of transfer of Shares rather than as of the date or dates upon which the Grantee would otherwise be taxable under Code Section 83(a), such Grantee shall deliver a copy of such election to the Company upon or prior to the filing such election with the U.S. Internal Revenue Service. Neither the Company nor any Affiliate thereof shall have any liability or responsibility relating to or arising out of the filing or not filing of any such election or any defects in its construction.

7.3 *Other Share-Based Awards.* The conditions and dates upon which other Share-based awards become vested and nonforfeitable and upon which the Shares underlying the restricted stock units and other Share-based awards may be issued, in all cases, will be subject to compliance with, or exemption from, Section 409A of the Code.

8. Amendment of Appendix.

This Appendix may be amended or terminated in accordance with the terms governing the amendment or termination of the ISAP; provided, however, that without the approval of the shareholders of the Company entitled to vote in accordance with applicable law, no amendment may be made that would: (i) increase the aggregate number of Shares that may be issued under this Appendix upon the exercise of Incentive Stock Options; (ii) change the classification of individuals eligible to receive Incentive Stock Options under this Appendix; (iii) extend the term of the ISAP under Sections 16 and 17 of the ISAP; or (iv) require shareholder approval in order to continue to comply with Section 422 of the Code to the extent applicable to Incentive Stock Options.

9. Compliance with Code Section 409A.

Although the Company does not guarantee to a Grantee any particular tax treatment of Awards, Awards will be designed and operated in such a manner that is intended to be exempt from the application, or in compliance with the requirements, of Code Section 409A. Each Award granted pursuant to the ISAP, this Appendix and the applicable Award Agreement is intended to comply with (or be exempt from) the requirements of Code Section 409A and any ambiguities or ambiguous terms herein will be construed and interpreted in accordance with such intent. In no event whatsoever shall the Company be liable for any additional tax, interest or penalties that may be imposed on the Grantee by Section 409A of the Code or for any damages for failing to comply with Section 409A of the Code.

* * *

Approved by the Company's Shareholders: _____ __, 2022

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
KI Biopharma LLC	Delaware, USA
Kamada Inc.	Delaware, USA
Kamada Plasma LLC	Delaware (wholly owned by Kamada Inc.), USA
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: March 15, 2022

/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: March 15, 2022

/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, 2021 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: March 15, 2022

/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, 2021 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: March 15, 2022

/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 March 15, 2022, 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, 2021.

/s/ KOST FORER GABBAY & KASIERER

A member of Ernst & Young Global

Tel Aviv, Israel
March 15, 2022