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

FORM 20-F

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

OR

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

For the fiscal year ended **December 31, 2020**

OR

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

OR

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

Date of event requiring this shell company report _____

Commission file number **001-37643**

Purple Biotech Ltd.
(Exact name of Registrant as specified in its charter)

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

Israel
(Jurisdiction of incorporation or organization)

4 Oppenheimer Street
Science Park
Rehovot 7670104, Israel
(Address of principal executive offices)

Gil Efron, Deputy Chief Executive Officer and Chief Financial Officer
4 Oppenheimer Street
Science Park
Rehovot 7670104, Israel
Tel: +972-3-933-3121; Fax: +972-153-39333121
(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 class	Trading Symbols	Name of each exchange on which registered
American Depositary Shares, each representing 10 Ordinary Shares [(1)]	**PPBT**	**NASDAQ Capital Market**

(1) Evidenced by American Depositary Receipts.

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None
(Title of Class)

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: 17,210,574 Ordinary Shares, no par value (including 1 share held in treasury)

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 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. ☐

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 Financing 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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Unless the context otherwise indicates or requires, all references to:

- the terms "Registrant," "Company," "we," "us," "our," "our company" and similar designations refer to Purple Biotech Ltd., together with (i) its former wholly-owned subsidiary, Kitov Pharmaceuticals, (ii) its majority owned subsidiary, TyrNovo, and (iii) its wholly owned subsidiary, FameWave, except where otherwise stated or where it is clear that the terms mean only Purple Biotech Ltd. exclusive of any subsidiaries,

- "Kitov Pharmaceuticals" refers to Kitov Pharmaceuticals Ltd., the Registrant's now dissolved wholly-owned subsidiary, which merged with and into the Registrant upon completion of the merger between the Registrant and Kitov Pharmaceuticals in December 2017, with the Registrant remaining as the surviving entity,

- "TyrNovo" refers to TyrNovo Ltd., the majority owned subsidiary of Purple Biotech,

- "FameWave" refers to FameWave Ltd., the wholly owned subsidiary of Purple Biotech,

- the terms "dollar", "US$" or "$" refer to U.S. dollars, the lawful currency of the United States of America,

- the terms "Euro" or "€" refer to the Euro, the lawful currency of the European Union member states,

- the terms "NIS" refer to the New Israeli Shekel, the lawful currency of the State of Israel,

- "ordinary shares," "our shares" and similar expressions refer to the Registrant's ordinary shares, no par value per share,

- "ADSs" refer to the Registrant's American Depositary Shares,

- the "Companies Law" refer to Israel's Companies Law, 5759-1999, as amended,

- the "SEC" refer to the United States Securities and Exchange Commission,

- "NASDAQ" refer to The NASDAQ Capital Market, except where otherwise stated or where it is clear that the term means any of the NASDAQ exchanges, and

- the "TASE" refer to the Tel Aviv Stock Exchange.

Unless otherwise indicated, all information contained in this Annual Report on Form 20-F gives retrospective effect to:

- Effective as January 4, 2019, we effected a consolidation of our share capital at a ratio of 1:20, such that: (i) each 20 ordinary shares of Purple Biotech were consolidated into one ordinary share of Purple Biotech and (ii) each 20 options of Purple Biotech (tradable and non-tradable) exercisable into ordinary shares outstanding immediately prior to the consolidation were consolidated into one option exercisable into one ordinary share of Purple Biotech at an exercise price equal to the pre-consolidation exercise price multiplied by 20.

- Effective as of August 21, 2020, we effected a change in the ratio of ordinary shares to each of our ADSs, such that the ratio of ADSs to ordinary shares changed from one (1) ADS representing one (1) ordinary share to a new ratio of one (1) ADS representing ten (10) ordinary shares. All ADS numbers in this Annual Report on Form 20-F are reflected on a post-ratio change basis.

Glossary of Industry Terms

Additionally, for convenience, the following terms used in this Annual Report on Form 20-F are defined as follows:

"API"	**Active Pharmaceutical Ingredient** – any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug product, becomes one active ingredient in the drug product.
"approved product"	A product that has been approved for commercialization by a regulatory authority.
"BLA"	**Biologics License Application** –A request for permission to market a new biological product.
"**cGMP**"	**Current Good Manufacturing Practice** – minimum requirements of the FDA and other regulatory authorities for the methods, facilities, and controls used in the manufacturing, processing, and packing of a drug product that is intended for human use to ensure that the product is safe for use and has the ingredients and strength that it claims to have.
"Clinical"	Pertaining to human studies.
"**EGFR**"	**Epidermal Growth Factor Receptor** (EGFR; ErbB-1; HER1 in humans) is a transmembrane protein that is a receptor for members of the epidermal growth factor family (EGF family) of extracellular protein ligands.
"FDA"	United States Food and Drug Administration.
"FIH"	First in human study.
"Formulation"	All the active and inactive materials contained in a final medical product.
"IND"	**Investigational New Drug (Application) –** an application to test an experimental drug in human beings and that requires clearance by the FDA for clinical trials to be initiated.
"mTOR"	A class of drugs that inhibit the mechanistic target of rapamycin (mTOR), which is a serine/threonine-specific protein kinase that belongs to the family of phosphatidylinositol- 3 kinase.
"NDA"	**New Drug Application -** an application submitted to the FDA to approve marketing a new drug.
"PDX"	An animal model in which patient-derived tumor tissue at low passage are implanted in animals, used to conserve original tumor characteristics and to provide relevant predictive insights into clinical outcomes when evaluating new cancer therapies.
"Preclinical"	Drug development studies performed outside of a human living organism or cell, using living cells, or appropriate animal models. The studies begin before trials in humans and assess safety, toxicity, and efficacy. Since drug development is dynamic, Preclinical studies are performed throughout the drug development lifecycle.
"Pharmacokinetics", **"PK"**	The study of the absorption, distribution, metabolism and excretion of a drug from the body; the pharmacokinetic indices provide, among other things, information on the extent and time of the patient's exposure to the material. It is the study of how the body affects the drug.
"therapeutic candidate"	A product that is undergoing development, preclinical trials, clinical trials and/or has a pending NDA in review by the FDA or similar marketing application being reviewed by a foreign regulatory authority but has not been approved for commercialization.

Trademarks

We have proprietary rights to trademarks used in this Annual Report on Form 20-F that are important to our business, some of which are registered under applicable intellectual property laws. Solely for convenience, trademarks and trade names referred to in this Annual Report may appear without the "®" or "™" symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent possible under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Each trademark, trade name or service mark of any other company appearing in this Annual Report on Form 20-F is the property of its respective holder.

FORWARD-LOOKING STATEMENTS

Some of the statements under the sections entitled "Item 3. Key Information — D. Risk Factors," "Item 4. Information on the Company," "Item 5. Operating and Financial Review and Prospects" and elsewhere in this Annual Report on Form 20-F may include forward looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates", "believes", "could", "estimates", "expects", "intends", "may", "plans", "potential", "predicts", "projects", "should", "will", "would", and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. In addition, the section of this Annual Report on Form 20-F entitled "Item 4. Information on the Company" contains information obtained from independent industry and other sources. You should not put undue reliance on any forward-looking statements. Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to:

- the initiation, timing, progress and results of our research, manufacturing, preclinical studies, clinical trials, and other therapeutic candidate development efforts, as well as the extent and number of additional studies that we may be required to conduct;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory clarity and approvals for our therapeutic candidates and the timing of other regulatory filings and approvals;
- our ability to obtain approvals for marketing of Consensi in other territories than the U.S.;
- a delay or rejection of an IND, NDA or BLA for one or more of our therapeutic candidates;
- our ability to maintain compliance with the NASDAQ listing standards;
- the regulatory environment and changes in the health policies and regimes in the countries in which we operate including the impact of any change in regulation and legislation that could affect the pharmaceutical industry, and the difficulty of predicting actions of the FDA or any other applicable regulator of pharmaceutical products;
- the research, manufacturing, preclinical and clinical development, commercialization, and market acceptance of our therapeutic candidates;
- our ability to successfully acquire, develop or commercialize our pharmaceutical products;
- the ability of our commercialization partners to successfully achieve substantial sales for our drug products;
- our ability to establish and maintain corporate collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model, strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, revenues, capital requirements and our needs for additional financing;
- the impact of competitive companies, technologies and our industry; and
- the impact of the public health, political and security situation in Israel, the U.S. and other countries in which we may operate or obtain approvals for our products or our business.

Our ability to predict our operating results or the effects of various events on our operating results is inherently uncertain. Therefore, we caution you to review carefully the risks and uncertainties described under the heading "Item 3. Key Information – D. Risk Factors" in this Annual Report on Form 20-F for a discussion of these and other risks that relate to our business and investing in Purple Biotech's ADSs and ordinary shares. Such factors and many other factors beyond our control could cause our actual results, performance or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by the forward-looking statements. The forward-looking statements contained in this Annual Report on Form 20-F are expressly qualified in their entirety by this cautionary statement.

SUMMARY OF RISK FACTORS

The following is a summary of some of the principal risks we face. The list below is not exhaustive, and investors should read the "Risk Factors" section included in Item 3 in full.

- We are a pharmaceutical company with a history of operating losses. We expect to incur significant additional losses in the future and may never be profitable.
- Our limited operating history as a pharmaceutical research and development company makes it difficult to evaluate our business and prospects, and we depend on the success of a limited portfolio of products for our revenue, which could impair our ability to achieve profitability.
- We will need to raise additional capital to achieve our strategic objectives of developing and commercializing our therapeutic candidates, as well as to acquire or in-license additional therapeutic candidates, and our long-term capital requirements are uncertain and subject to numerous risks.
- If we and/or our potential commercialization partners are unable to obtain and maintain FDA and/or other foreign regulatory authority approval for our therapeutic candidates, we and/or our potential commercialization partners will be unable to commercialize our therapeutic candidates.
- Our clinical trials may fail to demonstrate adequately the safety and efficacy of our therapeutic candidates, which would prevent or delay regulatory approval and commercialization.
- Our drug candidates may cause undesirable side effects or have other properties that could halt clinical development, prevent regulatory approval, limit commercial potential, or result in significant negative consequences.
- If we do not establish collaborations for our oncology therapeutic candidates or any other therapeutic candidates that we may develop or acquire in the future, or otherwise raise substantial additional capital, we will likely need to alter our development and any commercialization plans.
- Any collaborative arrangements that we establish may not be successful or we may otherwise not realize the anticipated benefits from these collaborations.
- Unexpected difficulties or delays in successfully developing, acquiring or commercializing combination products and new drugs could have an adverse effect on our business, financial condition and results of operations.
- We rely mainly on third parties to conduct our chemistry manufacturing and controls, research and development, preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including, but not limited to, failing to conform with quality standards for our drug candidates. which may endanger our clinical trial participants, and/or to meet established deadlines for the completion of such studies and trials.
- The manufacture of our drug candidates is complex, and we may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities. If we or any of our third-party manufacturers encounter such difficulties, our ability to supply drugs for clinical trials or our products (if approved) for patients on a timely basis could be materially delayed or adversely affected. In addition, this may cause an increase in costs that could result in our not being able to maintain a commercially viable cost structure.
- Pre-clinical studies and clinical trials may involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future results.
- We will depend on a joint collaboration partner to conduct clinical trials with CM24, and we may enter into future collaboration agreements with collaboration partners to develop and conduct clinical trials with, obtain regulatory approvals for, and market and sell our therapeutic candidates. If such collaboration fails to perform as expected, our clinical trials and/or development plans will be delayed and we will be required to seek other collaboration partners, which we may not be able to engage in a timely manner, or at all;
- Because CM24 and NT219 each represents a novel approach to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third-party reimbursement coverage and the commercial potential of CM24 and NT219.
- The recent COVID-19 outbreak may adversely affect our revenues, results of operations and financial condition.
- If third-party payers do not adequately reimburse customers for our Consensi drug product, or our oncology therapeutic candidates, if approved, or any of other therapeutic candidates that may be approved for marketing in the future, they might not be purchased or used, and our revenues and profits will not develop or increase.
- Legal proceedings or third-party claims of intellectual property infringement and other legal challenges may require us to spend substantial time and money and could prevent us from or delay us in developing or commercializing our therapeutic candidates. An adverse result in any infringement claim or other legal challenges could have a material adverse effect on our business, results of operations and financial condition.
- We may be unable to adequately protect or enforce our rights to intellectual property, causing us to lose valuable rights. Loss of any of our intellectual rights may lead us to lose market share and could have an adverse effect on our business, results of operations and financial condition.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. **Directors and Senior Management**

Not applicable

B. **Advisors**

Not applicable

C. **Auditors**

Not applicable

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The following table sets forth our selected consolidated financial data for the periods ended and as of the dates indicated. The following selected historical consolidated financial data should be read in conjunction with "Item 5. Operational and Financial Review and Prospects" and other information provided elsewhere in this Annual Report on Form 20-F and our consolidated financial statements and related notes. The selected consolidated financial data in this section is not intended to replace the consolidated financial statements and is qualified in its entirety thereby.

The selected consolidated statements of operations for the three years ended December 31, 2020, 2019 and 2018, and our selected consolidated statements of financial position as of December 31, 2020 and 2019 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 20-F. The selected consolidated statements of operations data for the years ended December 31, 2017 and 2016, and the selected consolidated statements of financial position data as of December 31, 2018, 2017 and 2016, have been derived from our audited consolidated financial statements not included in this Annual Report on Form 20-F. We prepare our consolidated financial statements in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standard Board ("IASB"). Our historical results are not necessarily indicative of results to be expected in any future periods. You should read this information together with the section of this Annual Report on Form 20-F entitled "Item 5. Operating and Financial Review and Prospects" and our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 20-F.

	Year Ended December 31,				
	2020	2019	2018	2017	2016
	(U.S. Dollars in thousands)				
Consolidated Statement of Operations:					
Revenues	1,000	1,000	1,000	100	-
Research and development expenses	7,488	2,674	5,268	4,640	4,180
Sales, general and administrative expenses	6,306	6,078	5,195	6,397	3,003
Reimbursement of legal fees	(182)	(596)	(743)	-	-
Other expenses (income)	-	-	(894)	1,029	-
Operating loss	12,612	7,156	7,826	11,966	7,183
Financing expense (income), net	15,462	(1,479)	(2,257)	947	4,942
Tax expenses	-	216			
Loss for the year	28,074	5,893	5,569	12,913	12,125
Loss attributable to:					
Owners of the Company	27,999	5,850	5,200	12,177	12,125
Non - Controlling interests	75	43	369	736	
Loss per ordinary share:[(1)]					
Basic and diluted	(2.44)	(3.00)	(3.9)	(13.7)	(21.1)
Weighted average number of ordinary shares used in computing basic and diluted loss per share (in thousands):	11,500	1,937	1,420	945	576

(1) Basic loss per ordinary share is calculated by dividing the loss attributable to shareholders by the weighted average number of ordinary shares outstanding during the period. There are no differences between basic and diluted loss per ordinary share since there are no dilutive potential ordinary shares.

	As of December 31,				
	2020	2019	2018	2017	2016
	(U.S. Dollars, in thousands)				
Statement of Financial Position Data:					
Cash and cash equivalents	11,247	4,385	5,163	3,947	6,758
Working capital (*)	56,184	4,756	5,200	4,010(*)	13,625
Total assets	83,803	14,718	14,723	14,183	14,914
Total liabilities	4,051	(3,859)	(3,719)	(5,495)(*)	(1,529)
Accumulated loss	(77,521)	(49,522)	(43,672)	(38,472)(*)	(26,200)
Total equity	79,752	10,859	11,004	8,688(*)	13,385

(*) Working capital is defined as current assets less current liabilities.

	As of December 31,				
	2020	2019	2018	2017	2016
	(U.S. Dollars, in thousands)				
Adjusted operating loss:					
Operating loss for the year	12,612	7,156	7,826	11,966	7,183
Less ESOP expenses	(2,645)	(1,273)	(773)	(2,308)	(400)
Adjusted operating loss	9,967	5,883	7,053	9,658	6,783

Adjusted operating loss is defined as operating loss, plus non-cash share-based compensation expenses. Our management believes that excluding non-cash charges related to share-based compensation provides useful information to investors because of its non-cash nature, varying available valuation methodologies among companies and the subjectivity of the assumptions and the variety of award types that a company can use under the relevant accounting guidance, which may obscure trends in our core operating performance. We present adjusted operating loss because we use this non-IFRS financial measures to assess our operational performance, for financial and operational decision-making, and as a means to evaluate period-to-period comparisons on a consistent basis. Management believes this non-IFRS financial measure is useful to investors because: (1) it allows for greater transparency with respect to key metrics used by management in its financial and operational decision-making; and (2) it excludes the impact of non-cash item that is not directly attributable to our core operating performance and that may obscure trends in the core operating performance of the business. Non-IFRS financial measures have limitations as an analytical tool and should not be considered in isolation from, or as a substitute for, our IFRS results. We expect to continue reporting non-IFRS financial measures, adjusting for the item described above, and we expect to continue to incur expenses similar to certain of the non-cash, non-IFRS adjustments described above. Accordingly, unless otherwise stated, the exclusion of this and other similar items in the presentation of non-IFRS financial measures should not be construed as an inference that these items are unusual, infrequent or non-recurring. Adjusted operating loss is not a recognized term under IFRS and do not purport to be an alternative to IFRS net operating loss as an indicator of operating performance or any other IFRS measure. Moreover, because not all companies use identical measures and calculations, the presentation of adjusted operating loss may not be comparable to other similarly titled measures of other companies.

B. **Capitalization and Indebtedness**

Not applicable.

C. **Reasons for the Offer and Use of Proceeds**

Not applicable.

D. Risk Factors

You should carefully consider the risks we describe below, in addition to the other information set forth elsewhere in this Annual Report on Form 20-F, including our consolidated financial statements and the related notes beginning on page F-1, which could materially adversely affect our business, financial condition and future results. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of Purple Biotech's ordinary shares and American Depositary Shares could decline.

Risks Related to Our Financial Condition and Capital Requirements

We are a pharmaceutical company with a history of operating losses. We expect to incur significant additional losses in the future and may never be profitable.

We are a pharmaceutical company, and we are focused on the development and commercialization of innovative pharmaceutical drugs. We have one FDA-approved drug, Consensi for which we have entered into commercialization agreements with respect to the United States and in several territories in Asia (subject to regulatory approval in such territories). We commenced commercial sales of Consensi in the United States in May 2020 but have not commenced drug sales in any other territory. Additionally, we currently have two oncology therapeutic candidates, NT219 and CM24, neither of which has been approved for marketing and they are not being sold, marketed or commercialized. Each will require additional preclinical and/or clinical trials or other testing before we can obtain regulatory approval, if we are able to obtain regulatory approval at all. We must obtain regulatory approval for NT219, CM24 or any other therapeutic candidate that we may develop or acquire in the future, before we can sell such therapeutic candidates. We have incurred losses from commencement of our pharmaceutical research and development activities through December 31, 2020 of approximately $$77.5 million as a result of research and development activities, clinical trial related activities, investment/acquisition activities, listing for trading and fund-raising related activities, selling, general and administrative, finance expenses and other expenses. We may incur significant additional losses as we continue to focus our resources on advancing NT219, CM24 or other therapeutic candidates that we may develop or acquire in the future. Our ability to generate revenue and achieve profitability depends mainly upon our ability, alone or with others, to successfully develop or acquire, and obtain the required regulatory approvals for, our oncology therapeutic candidates in the United States and various other territories and then to successfully commercialize our oncology therapeutic candidates; to successfully market and sell our FDA-approved drug Consensi in the United States through our U.S. commercialization partner; and to obtain, either by us or by our commercialization partners, the required regulatory approvals in various territories other than the United States and then commercialize and sell Consensi in such other territories. We may be unable to achieve any or all of these goals with regard to NT219, CM24 or any other therapeutic candidates that we may develop in the future and our FDA-approved drug Consensi. As a result, we may never be profitable or achieve significant or sustained revenues.

Our limited operating history as a pharmaceutical research and development company makes it difficult to evaluate our business and prospects, and we depend on the success of a limited portfolio of products for our revenue, which could impair our ability to achieve profitability.

We have a limited operating history as a pharmaceutical research and development company, and our operations to date have been limited primarily to developing, gaining regulatory approval, and commercializing Consensi; developing our NT219 and CM24 therapeutic candidates; research and development; raising capital; and recruiting scientific and management personnel and third party partners. Though we have plans for the development and acquisition of additional therapeutic candidate products, to date the only revenue we have received has been the initial milestone payments in connection with commercialization agreements for Consensi. We have not yet demonstrated an ability to successfully generate significant revenues from Consensi. We have also not yet demonstrated an ability to commercialize or obtain regulatory approval for our NT219 and CM24 therapeutic candidates. Our future growth and success depend upon the successful commercialization of Consensi and our oncology therapeutic candidates. If we are unable to achieve increased commercial acceptance of our products or obtain regulatory clearances or approvals for our therapeutic candidates and future products, or if we experience a decrease in the utilization of our products, our revenue would be adversely affected. Consequently, any predictions about our future performance may not be accurate, and you may not be able to fully assess our ability to complete development of or commercialize our therapeutic candidates, acquire other therapeutic candidates, obtain regulatory approvals, or achieve market acceptance or favorable pricing for our therapeutic candidates.

We will need to raise additional capital to achieve our strategic objectives of developing and commercializing our therapeutic candidates, as well as to acquire or in-license additional therapeutic candidates ***and our failure to raise sufficient capital would significantly impair our ability to fund our future operations, develop our therapeutic candidates, seek regulatory approval that is a prerequisite to selling any product, attract development or commercial partners and retain key personnel.***

Our business presently generates limited revenues, and we plan to continue expending substantial funds in research and development, including CMC, preclinical and clinical trials of our NT219 and CM24 therapeutic candidates, and for manufacturing of our FDA-approved drug Consensi, as well as to acquire or in-license additional therapeutic candidates. We plan to fund our future operations through commercialization and out-licensing of our products and therapeutic candidates and by either debt or equity financing. However, we cannot be certain that we will be able to raise capital on commercially reasonable terms or at all, or that our actual cash requirements will not be greater than anticipated. We may have difficulty raising needed capital or securing a development or commercialization partner in the future as a result of, among other factors, our lack of revenues from commercialization of the therapeutic candidates, as well as the inherent business risks associated with our company and present and future market conditions. In addition, global and local economic and geopolitical conditions may make it more difficult for us to raise needed capital or secure a development or commercialization partner in the future and may impact our liquidity. If we are unable to obtain future financing, we may be forced to delay, reduce the scope of, or eliminate one or more of our research, development or commercialization programs related to our therapeutic candidates or any other therapeutic candidates that we may acquire, in-license or develop in the future or to delay the acquisition or in-license of any additional therapeutic candidates, any of which may have a material adverse effect on our business, financial condition and results of operations. Moreover, to the extent we are able to raise capital through the issuance of debt or equity securities, it could result in substantial dilution to existing shareholders.

Our long-term capital requirements are uncertain and subject to numerous risks.

We estimate that so long as no significant revenues are generated from our oncology therapeutic candidates and our FDA-approved drug Consensi, we will need to raise substantial additional funds to develop and/or commercialize our therapeutic candidates and to acquire or in-license any additional therapeutic candidates, as our current cash and short-term investments are not sufficient to complete the research and development of our therapeutic candidates in their current phase of development and any additional therapeutic candidates that we may acquire, in-license or develop in the future, and to fund our related expenses. Our long-term capital requirements are expected to depend on many potential factors, including, among others:

- the costs of seeking out and acquiring or engaging in licensing or similar transactions for other oncological candidates;
- our ability to successfully complete the required CMC development for our oncology therapeutic candidates or any other therapeutic candidates that we may acquire or develop in the future;
- our ability to successfully commercialize our oncology therapeutic candidates, or any other therapeutic candidates that we may acquire or develop in the future, including securing commercialization agreements with third parties and favorable pricing and market share;
- the ability of our U.S. partner to successfully distribute and sell Consensi;
- our ability to successfully obtain approvals for marketing of Consensi in other territories than the U.S.;
- the progress, success and cost of our preclinical and/or clinical trials and research and development programs;
- the costs, timing and outcome of regulatory review and obtaining regulatory approval of our oncology therapeutic candidates or any other therapeutic candidates that we may acquire or develop in the future and addressing regulatory and other issues that may arise post-approval for such oncology therapeutic candidates or from commercializing Consensi;
- the costs of obtaining and enforcing our issued patents and defending intellectual property-related claims;
- the costs of developing and maintaining our third parties' cGMP manufacturing standards and our sales, marketing and distribution channels;
- our consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated;
- our ability to obtain recommendations and publish studies regarding the efficacy and/or safety of our approved products, or our oncology therapeutic candidates or any other therapeutic candidates that we may acquire or develop in the future that may be published by government agencies, professional organizations, academic or medical journals or other key opinion leaders;
- patient acceptance of and demand for Consensi;
- sufficient coverage and reimbursement by third-party payers; and
- maintaining FDA marketing approval of Consensi.

If we are unable to obtain approval, commercialize or out-license our oncology therapeutic candidates, or any other therapeutic candidates that we may acquire, in-license or develop in the future, maintain approval, or obtain future financing, we may be forced to delay, reduce the scope of, or eliminate one or more of our research and development programs related to the therapeutic candidates, which may have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Business and Regulatory Matters

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our therapeutic candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our therapeutic candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our therapeutic candidates. Before obtaining regulatory approvals for the commercial sale of any of our therapeutic candidates, we must demonstrate through lengthy, complex, and expensive preclinical testing and clinical trials that our therapeutic candidates are both safe and effective for use in each target indication. In particular, because some of our therapeutic candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for drug product approval will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of our therapeutic candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our therapeutic candidates may not be predictive of the results of later-stage clinical trials. The results of studies in one set of patients or line of treatment may not be predictive of those obtained in another. We expect that there may be greater variability in results for products processed and administered on a patient-by-patient basis, as anticipated for our therapeutic candidates, than for "off-the-shelf" products, like many other drugs. There is typically an extremely high rate of attrition from the failure of therapeutic candidates proceeding through clinical trials. Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most therapeutic candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our therapeutic candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of its therapeutic candidates.

Our drug candidates may cause undesirable side effects or have other properties that could halt clinical development, prevent regulatory approval, limit commercial potential, or result in significant negative consequences.

Undesirable side effects or adverse events caused by our drug candidates, or related to the combination therapies, could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable toxicities arise in the development of our drug candidates, the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our therapeutic candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business, financial condition and prospects significantly.

If we and/or our potential commercialization partners are unable to obtain FDA and/or other foreign regulatory authority approval for our therapeutic candidates, we and/or our potential commercialization partners will be unable to commercialize our therapeutic candidates.

Although we commenced sales of Consensi in the U.S. market in May 2020, to date we have not achieved significant sales in the U.S. or marketed, distributed or sold any therapeutic candidate or drug product in any other territory. In addition to the agreement we entered into to distribute Consensi in the U.S., we have entered into only two other out-licensing agreements for marketing, manufacturing and distribution of Consensi in South Korea and China, which are dependent upon achieving regulatory clearance or approval for Consensi in each of those respective countries. Our oncology therapeutic candidates are each subject to extensive governmental laws, regulations and guidelines relating to development, preclinical and clinical trials, manufacturing and commercialization of drugs. We may not be able to obtain regulatory approval for any of our therapeutic candidates in a timely manner or at all.

Any material delay in obtaining, or the failure to obtain, required regulatory approvals will increase our costs and materially and adversely affect our ability to generate future revenues. Any regulatory approval to market a therapeutic candidate may be subject to restrictive conditions of use, including cautionary information, thereby limiting the size of the market for the therapeutic candidate. We also are, and will be, subject to numerous regulatory requirements from both the FDA and foreign state agencies that govern the conduct of preclinical and clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. Moreover, approval by one regulatory authority does not ensure approval by other regulatory authorities in separate jurisdictions. Each jurisdiction may have different approval processes and may impose additional testing requirements for our therapeutic candidates than other jurisdictions. For example, even though the FDA has granted its approval to market Consensi for certain indications of use, the South Korean and/or the Chinese regulatory authorities may impose additional requirements or place other limitations on the indications for use in such countries before our licensee and distributors in such countries may commence manufacturing and selling Consensi. Additionally, the FDA or other foreign regulatory bodies may change their approval policies or adopt new laws, regulations or guidelines in a manner that delays or impairs our ability to obtain the necessary regulatory approvals to commercialize our therapeutic candidates.

Pre-clinical studies, CMC, and clinical trials may involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future results. We and/or our potential commercialization partners will not be able to commercialize our therapeutic candidates without developing CMC satisfactory to regulatory authorities, completing preclinical studies and clinical trials and then seeking to obtain regulatory approval if such trials show that our therapeutic candidates are safe and effective.

We have limited experience in conducting and managing the CMC, preclinical studies and clinical trials that are required to commence commercial sales of our therapeutic candidates. Developing and implementing CMC, and planning and conducting preclinical studies and clinical trials are expensive, complex, can take many years to complete and have uncertain outcomes. We cannot predict whether we, independently or through third parties, will encounter problems with any of the completed, ongoing or planned CMC, preclinical studies and/or clinical trials that will cause delays, including suspension of preclinical studies and/or clinical trials, delays in recruiting patients into the clinical trials, or delay of data analysis or release of the final report in our preclinical studies or clinical studies. The CMC, preclinical studies and clinical trials of our therapeutic candidates may take significantly longer to complete than is estimated. Failure can occur at any stage of the testing, and we may experience numerous unforeseen events during, or as a result of, the CMC, preclinical studies, and/or clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates.

In connection with the CMC, preclinical studies and clinical trials for our therapeutic candidates and other therapeutic candidates that we may seek to develop in the future, either on our own or through licensing or partnering agreements, we face various risks, including but not limited to:

- delays in manufacturing the drug substance and drug product for preclinical studies and clinical trials;
- delays in manufacturing the drug substance and drug product following NDA or BLA approval, if we receive such approval at all;

- delays in securing clinical investigators or trial sites for clinical trials that must be completed for us to obtain any approval that we seek;
- delays in receiving import or other government approvals to ensure appropriate drug supply;
- delays in obtaining institutional review board (human ethics committee) and other regulatory approvals to commence a clinical trial;
- negative or inconclusive results from preclinical and/or clinical trials;
- the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies and may not approve initiation of certain clinical trials;
- failure to manufacture our drug products, to maintain the drug products, or contamination to our drug products;
- an inability to monitor patients adequately during or after treatment;
- problems with investigator or patient compliance with the trial protocols;
- a therapeutic candidate may not prove safe or efficacious;
- there may be unexpected or even serious adverse events and side effects from the use of a therapeutic candidate;
- the results with respect to any therapeutic candidate may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the FDA or other foreign regulatory authorities;
- the results will leave only limited and/or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of the therapeutic candidate;
- the clinical trials may be delayed or not completed due to the failure to recruit suitable candidates or if there is a lower rate of suitable candidates than anticipated or if there is a delay in recruiting suitable candidates;
- changes to the current regulatory requirements related to clinical trials which can delay, hinder or lead to unexpected costs in connection with our receiving the applicable regulatory approvals; and
- the availability of other drugs that provide alternative and/or superior treatments to our drugs and drug candidates.

A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier preclinical studies and/or clinical trials. As such, we do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety sufficient to obtain regulatory approval to market our therapeutic candidates. If any of the preclinical studies and/or clinical trials of any therapeutic candidate do not produce favorable results, our ability to obtain regulatory approval for the therapeutic candidate may be adversely impacted, which will have a material adverse effect on our business, financial condition and results of operations.

If we do not establish collaborations for our oncology therapeutic candidates or any other therapeutic candidates that we may develop or acquire in the future, or otherwise raise substantial additional capital, we will likely need to alter our development and any commercialization plans.

Our drug development programs, including our commercialization of Consensi and the potential commercialization of our oncology therapeutic candidates, or any other therapeutic candidates that we may develop or acquire in the future, will require additional cash to fund expenses. As such, our strategy includes selectively partnering or collaborating with multiple pharmaceutical and biotechnology companies to assist us in furthering development and potential commercialization of our therapeutic candidates, in some or all jurisdictions. While we have entered into an exclusive marketing and distribution agreement with respect to the commercialization of Consensi in the U.S. and market and out-licensing agreements for marketing, manufacturing and distribution of Consensi in South Korea and China, we may not be successful in collaborations with other third parties on acceptable terms, or at all. In addition, if we fail to negotiate and maintain suitable development or commercialization agreements, we may have to limit the size or scope of our activities or we may have to delay one or more of our development or commercialization programs. Any failure to enter into or maintain development or commercialization agreements with respect to the development, marketing and commercialization of our therapeutic candidates or Consensi in foreign jurisdictions where we do not have approval for commercialization, or any other therapeutic candidates that we may develop or acquire in the future or failure to develop or acquire, market and commercialize such therapeutic candidates, or failure to market and commercialize our Consensi drug product in the U.S. market, will have an adverse effect on our business, financial condition and results of operation.

Any collaborative arrangements that we establish may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. We do not control third parties with whom we have or may have collaborative arrangements, and we rely on them to achieve results which may be significant to us. In addition, any future collaboration arrangements may place the development, manufacturing and commercialization of our Consensi drug product, our oncology therapeutic candidates or any other therapeutic candidates that we may develop or acquire in the future, outside our control, and may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Our collaborative arrangements require us to rely on external consultants, advisors, experts and service providers for assistance in several key functions, including preclinical and clinical development, manufacturing, regulatory, market research, and intellectual property. We do not control these third parties, but we rely on them to achieve results, which may be significant to us. Additionally, we are responsible for any quality or regulatory issue that a collaborator may have that affects one or more of our therapeutic candidates. Relying upon collaborative arrangements to develop and/or commercialize our Consensi drug product, our oncology therapeutic candidates or any other therapeutic candidates that we may develop or acquire in the future subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our collaborators may devote to our drug product or therapeutic candidates;
- we may be held liable should a collaborator fail to comply with applicable laws, rules, or regulations when performing services for us;
- our collaborators may experience financial difficulties or changes in business focus;
- our collaborators may experience quality or regulatory issues that negatively affect our therapeutic candidates;
- our collaborators may fail to secure adequate commercial supplies in a timely manner for our drug products upon marketing approval, if at all;
- our collaborators may have a shortage of qualified personnel;
- we may be required to relinquish important rights, such as local trademark, marketing and distribution rights;

- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;

- under certain circumstances, a collaborator could move forward with a competing therapeutic candidate developed either independently or in collaboration with others, including our competitors; and

- collaborative arrangements are often terminated or allowed to expire, which could delay and increase the cost of development of our therapeutic candidates.

If any of these or other scenarios materialize, they could have an adverse effect on our business, financial condition or results of operations.

Our current business model is based largely upon the development or acquisition and commercialization of new combination products and new drug candidates that have mostly not yet been administered to humans. Unexpected difficulties or delays in successfully developing, acquiring or commercializing such combination and new drugs could have an adverse effect on our business, financial condition and results of operations.

We are currently focused on combination products and drug candidates that have mostly not yet been administered to humans. Consensi has the combination of generic substances celecoxib and amlodipine besylate that had not previously been combined into one FDA-approved drug product or used at all in a clinical setting outside the scope of the clinical trials before we obtained FDA-approval to commercialize Consensi. We cannot be certain that the market will consider our Consensi drug product to be superior to the current gold standard of care or to treatment with the separate drug components rather than in combination.

The previous owners of the CM24 conducted the first human clinical trials for this therapeutic candidate, which were initiated in 2015, and discontinued in 2017. In the second half of 2020 we commenced a phase 1/2 study of NT219 as a single agent in patients with solid tumors, followed by a dose escalation phase of NT219 in combination with cetuximab for the treatment of recurrent and/or metastatic solid tumors and squamous cell carcinoma of the head and neck cancer or colorectal adenocarcinoma, and an expansion phase of NT219 at its recommended phase 2 level in combination with cetuximab in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck. However, we cannot be certain whether NT219 or CM24 will be safe and efficacious when used in either monotherapy settings or in combination with other known cancer treatments.

In addition, we cannot be certain that the FDA or any foreign regulatory body will consider our oncology therapeutic candidates, whether alone or combined with a particular cancer treatment, or any other therapeutic candidate that we may develop or acquire in the future to be superior to the current gold standard of care. Any delays in perfecting the combination, the production of the combination, or in market acceptance of the combination or new drug candidates could have an adverse effect on our business, financial condition and results of operations.

In addition, as part of our strategy for growth, we may consider the acquisition of therapeutic candidates at various stages of development and in a variety of therapeutic areas, and we may also consider the acquisition or marketing rights of approved drug products as well. However, we may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully into our business. In this regard, acquisitions involve numerous risks, including difficulties in the integration of the acquired therapeutic candidates and/or drug product and the diversion of management's attention from other business concerns. Although we will endeavor to evaluate the risks inherent in any particular transaction, there can be no assurance that we will properly ascertain all such risks. In addition, acquisitions could result in the incurrence of substantial additional indebtedness and other expenses or in potentially dilutive issuances of equity securities. There can be no assurance that difficulties encountered with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

We rely mainly on third parties to conduct our CMC, research and development, preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including, but not limited to, failing to conform quality standards for our drug candidates, which may endanger our clinical trial participants, and/or fail to meet established deadlines for the completion of such studies and trials.

We do not have the ability independently to conduct CMC, research and development, preclinical studies or clinical trials for our product candidates, and we rely mainly on third parties, such as contract manufacturing organizations, contract research organizations, medical institutions, contract laboratories, current and potential development or commercialization partners, clinical investigators and independent study monitors, to perform these functions. Our reliance on these third parties for development activities reduces our control over these activities.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Although we have, in the ordinary course of business, entered into agreements with these third parties, we continue to be responsible for confirming that each of our preclinical studies and clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and other regulatory agencies require us and our applicable third-party collaborators to comply with regulations and standards, commonly referred to as current good laboratory practices (cGLP), current good manufacturing practices (cGMP), and current good clinical practices (cGCP), for manufacturing and conducting, recording and reporting the results of preclinical and clinical trials to assure that data and reported results are credible and accurate and that the clinical trial participants are adequately protected. We cannot guarantee that our third-party collaborators will remain compliant with the applicable regulations. Regulatory authorities in other jurisdictions may have similar responsibilities and requirements. Our reliance on third parties does not relieve us of these responsibilities and requirements.

To date, we believe our contract manufacturing organizations, contract research organizations and other third-party entities that support our manufacturing, research and development, preclinical or clinical practices with which we are working have generally performed well. However, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not meet our deadlines or we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, finding replacements may result in a delay of clinical trials and/or commercialization of products and additional costs. Accordingly, we may be delayed in obtaining regulatory approvals for our oncology therapeutic candidate or any therapeutic candidate that we may develop or acquire in the future and we may be delayed in our efforts to successfully commercialize such therapeutic candidates for targeted diseases or fail to maintain marketing authorization to our drug products.

In addition, we rely substantially on third-party data managers for the CMC, preclinical study and clinical trial data that we present to regulatory authorities in order to obtain marketing authorizations. Although we attempt to audit and control the quality of third-party data, we cannot guarantee the authenticity or accuracy of such data, nor can we be certain that such data has not been fraudulently generated. There is no assurance that these third parties will pass FDA or regulatory audits, which could delay or prevent regulatory approval or cause revocation of already approved marketing authorization.

If third parties do not manufacture our current therapeutic candidates or any other therapeutic candidate that we may develop or acquire in the future in sufficient quantities in the required timeframe, at the required quality standards and at an acceptable cost, clinical development and commercialization of our therapeutic candidates would be delayed.

We do not currently own or operate manufacturing facilities, and we rely, and expect to continue to rely, on third parties to manufacture preclinical, clinical and commercial quantities of our oncology therapeutic candidates or any other therapeutic candidate that we may develop or acquire in the future. Our reliance on third parties includes our reliance on them to manufacture such therapeutic candidates at a required standard of quality, including quality assurance related to regulatory compliance. Our current and anticipated future reliance upon others for the manufacture of our oncology therapeutic candidates or any other therapeutic candidate that we may develop or acquire in the future may adversely affect our future profit margins, if any, and our ability to develop such therapeutic candidates and commercialize any such therapeutic candidates at a required standard of quality and on a timely and competitive basis.

We may not be able to maintain our existing or future third party manufacturing arrangements on acceptable terms, if at all. If for some reason our existing or future manufacturers do not perform as agreed or expected, or our existing or future manufacturers otherwise terminate their arrangements with us, we may be required to replace them. Although we are not completely dependent upon our existing manufacturing agreements since we could replace them with other third party manufacturers, we may incur added costs and delays in identifying, engaging, qualifying and training any such replacements, and in receiving regulatory approval for such replacements.

We rely on third party contract vendors to manufacture and supply us with APIs to be compliant with the International Conference of Harmonization Q7 guidance and applicable laws and regulations, in the quantities we require on a timely basis.

We currently do not manufacture any API ourselves. Instead, we rely on third-party vendors for the manufacture and supply of our APIs that are used to formulate our Consensi drug product and our oncology therapeutic candidates. While there are many potential API manufacturers and suppliers in the market, if these manufacturers or suppliers are incapable or unwilling to meet our current or future needs on acceptable terms or at all, or the current or future demand of the public, if any, we could experience delays in manufacturing of our drug product or in conducting clinical trials for NT219, CM24 or any other therapeutic candidate that we may develop or acquire in the future, and incur additional costs.

While there may be several alternative manufacturers or suppliers of API in the market, we have not conducted extensive audits and investigations into the quality or availability of their APIs. In addition, we may acquire therapeutic candidates which already have long term commitments to a specific API supplier. As a result, we can provide no assurances that supply sources will not be interrupted from time to time. Changing API manufacturers or suppliers or finding and qualifying new API manufacturers or suppliers can be costly and take a significant amount of time. Many APIs require significant lead time to manufacture. There can also be challenges in maintaining similar quality or technical standards from one manufacturing batch to the next.

If we are not able to find stable, reliable manufacturers or suppliers of our APIs, we may not be able to produce enough supplies of our Consensi drug product to meet the current or future demands of the public or produce enough supplies of our oncology therapeutic candidates to meet our needs for further development and/or to conduct clinical trials, which could affect our business, financial condition and results of operation.

We anticipate continued reliance on third-party manufacturers if we are successful in obtaining marketing approval from the FDA and/or other regulatory agencies for NT219, CM24 or any other therapeutic candidates we may develop or acquire in the future.

To date, our NT219 and CM24 therapeutic candidates has been manufactured in relatively small quantities by third-party manufacturers. Once our oncology therapeutic candidates and/or any other therapeutic candidate that we may develop or acquire in the future is approved for marketing and commercial sale, if at all, we still expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of such approved therapeutic candidates. These manufacturers may not be able successfully to increase the manufacturing capacity for any such therapeutic candidates that may be approved in the future in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable successfully to increase the manufacturing capacity for our oncology therapeutic candidates or any therapeutic candidate that we may develop or acquire in the future, or we are unable to establish alternative manufacturing capabilities and in a timely manner, the commercial launch of any such therapeutic candidates that are approved in the future may be delayed or there may be a shortage in supply.

We anticipate continued reliance on third-party manufacturers to manufacture our Consensi drug product at commercial scale to meet the demand in the United States or any foreign jurisdiction in which we may commercialize our Consensi drug product in the future.

Prior to our U.S. launch of Consensi we engaged a third party supplier for the manufacturing of sufficient quantities of Consensi at commercial scale. We anticipate that we will continue to rely on our third-party manufacturer to manufacture our Consensi drug product at commercial scale under cGMP conditions. Our third-party supplier may not be able to successfully increase the manufacturing capacity for our Consensi drug product to meet the demand in the United States. Though we can attempt to ensure the availability of suppliers or manufacturers for Consensi, the number of suppliers with suitable manufacturing capacity and capability is often very limited, and therefore we may be dependent on one or a few such suppliers. Furthermore, any changes to the manufacturing process to increase the manufacturing capacity for Consensi, including changing or including additional manufacturers, or any other changes with respect to manufacturing may require additional validation studies, which the FDA must review and approve. If third-party manufacturers are unable to successfully increase the manufacturing capacity for Consensi or we are unable to establish alternative manufacturing capabilities, our efforts to meet the demand for our Consensi drug product in the United States may be delayed or there may be a shortage in supply.

We and our third-party manufacturers are, and will be, subject to regulations of the FDA and other foreign regulatory authorities.

We and our third-party contract manufacturers are, and will be, required to adhere to laws, regulations and guidelines of the FDA and other foreign regulatory authorities setting forth cGMPs. These laws, regulations and guidelines cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our Consensi drug product and our oncology therapeutic candidates when we initiate their clinical trials. We and our manufacturers may not be able to comply with applicable laws, regulations and guidelines. We and our manufacturers are and will be subject to unannounced inspections by the FDA, state regulators and similar foreign regulatory authorities outside the U.S. Our failure, or the failure of our third-party manufacturers, to comply with applicable laws, regulations and guidelines could result in the imposition of sanctions on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our therapeutic candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our therapeutic candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of our therapeutic candidates and materially and adversely affect our business, financial condition and results of operations.

Our FDA-approved Consensi drug product and our oncology therapeutic candidates and/or any other therapeutic candidate that we may develop or acquire in the future, if approved, will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign laws, regulations and guidelines, we could lose the FDA and/or other regulatory agencies' approval(s) we have obtained (or will obtain, if any), and our business would be seriously harmed.

Our FDA-approved Consensi drug product is subject to ongoing post-marketing surveillance programs and regulatory review. In addition, if our oncology therapeutic candidates and/or any other therapeutic candidate that we may develop or acquire in the future receives regulatory approval to commercialize, such therapeutic candidate will be subject to ongoing post-marketing surveillance programs and regulatory review. We and our commercialization partners, as applicable, are subject to ongoing reporting obligations, including pharmacovigilance, or drug safety, and our manufacturing operations, and those of contract manufacturers that we select, will be subject to continuing regulatory review, including inspections by the FDA and other foreign regulatory authorities if a product is approved for commercialization in such foreign jurisdictions. The results of this ongoing review may result in the withdrawal of an approved product from the market, the interruption of manufacturing operations or the imposition of labeling or marketing limitations. In addition, since many more patients are treated with drugs following their marketing post-approval, unanticipated adverse reactions or serious adverse reactions that were not observed in preclinical and/or clinical trials may be observed during the commercial marketing of a drug product.

As we move forward with commercializing drug products, we may also periodically discuss with the FDA and other regulatory authorities certain clinical, regulatory and manufacturing matters and, our views may, at times, differ from those of the FDA and other regulatory authorities. If we are required to conduct additional clinical trials or other testing of an approved drug product, we may face substantial additional expenses, and/or we have our approval to commercialize a drug product revoked by the FDA or a foreign regulatory body, should we obtain approval to commercialize in such foreign jurisdiction.

In addition, the manufacturer and the facilities that we or our commercialization partners use or may use to manufacture drug products will be subject to periodic and unannounced review and inspection by the FDA and other foreign regulatory authorities. Later discovery of previously unknown problems with a drug product or a therapeutic candidate, the manufacturer or manufacturing process, or failure to comply with our post-approval requirements, rules and regulatory requirements, may result in actions such as:

- restrictions on such drug product, therapeutic candidate, manufacturer or manufacturing process;
- issuance of Form 483 inspection observations, untitled letters, warning letters from the FDA or other foreign regulatory authorities;
- withdrawal of the product or therapeutic candidate from the market;
- suspension or withdrawal of regulatory approvals;

- refusal to approve pending applications or supplements to approved applications that we or our potential commercialization partners submit;
- voluntary or mandatory recall;
- refusal to permit the import or export of our therapeutic candidates;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties and fines; or
- adverse publicity or changes to the drug's labeling.

The FDA or foreign regulatory authorities' policies may change, or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our oncology therapeutic candidates or regulations may be enacted or changed that could hinder our ability to commercialize our Consensi drug product. If we, or our current or potential commercialization partners, suppliers, third party contractors or clinical investigators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or the adoption of new regulatory requirements or policies, we or our potential commercialization partners may lose marketing approval for our Consensi drug product and/or our oncology therapeutic candidates or any other therapeutic candidate that we may develop or acquire in the future that obtain regulatory approval, resulting in decreased or lost revenue from milestones, product sales or royalties and could also result and other civil or criminal sanctions, including fines and penalties.

Regulatory approval of our Consensi drug product is limited by the FDA and similar foreign authorities to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and the promotion of Consensi (or other products or product candidates, as applicable) for off-label uses, or in a manner that otherwise violates applicable FDA regulations, could adversely affect our business.

Any regulatory approval of therapeutic candidates is limited to those specific diseases and indications for which such therapeutic candidates have been deemed safe and effective by the FDA or similar foreign authorities. We received FDA approval to commercialize Consensi only for the simultaneous treatment of two clinical conditions: pain caused by osteoarthritis and hypertension, or high blood pressure. Marketing or commercializing Consensi to treating a new symptom, or indication that is not pain caused by osteoarthritis and hypertension would be considered promotion of off-label, or unapproved use, and would require us to file a supplemental new drug application and obtain regulatory approval. We rely on physicians to prescribe and administer Consensi as the product labeling directs and for the indications described on the labeling. To the extent any physicians prescribe Consensi to patients for off-label uses, or the use of Consensi departs from the approved uses, this may increase the risk of injury or other adverse events to the patients and product liability claims brought against us. Product liability claims are expensive to defend regardless of merit and could result in substantial damage awards against us or harm our reputation. Furthermore, the use of Consensi for indications other than those approved by the FDA or foreign authorities, if any, may not effectively treat the conditions associated with the off-label use, which could harm our reputation in the marketplace among physicians and patients, adversely affecting our operations.

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 Consensi is limited to those indications that are specifically approved by the FDA or other regulatory authorities. Although regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies on the subject of off-label use. If the promotional activities related to Consensi fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA or other regulatory authorities. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can lead to other negative consequences that could adversely affect our operations, such as the suspension or withdrawal of Consensi from the market, enforcement letters, and corrective actions. Other regulatory authorities may impose separately penalties including, but not limited to, fines, disgorgement of money, operating restrictions, or criminal prosecution.

The FDA also requires that our and our distribution partners' sales and marketing efforts, as well as promotions, comply with various laws and regulations. Prescription drug promotions must be consistent with and not contrary to labeling, present "fair balance" between risks and benefits, be truthful and not false or misleading, be adequately substantiated (when required), and include adequate directions for use. In addition to the requirements applicable to approved drug products, we may also be subject to enforcement action in connection with any promotion of an investigational new drug. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, may not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug candidate.

If the FDA investigates the marketing and promotional materials or other communications for our current or future commercial products and finds that any of our commercial products are being marketed or promoted in violation of the applicable regulatory restrictions, we and our distribution partners could be subject to FDA enforcement action. Any enforcement action (or related lawsuit, which could follow such action) brought against us in connection with alleged violations of applicable drug promotion requirements, or prohibitions, could harm our business and our reputation, as well as the reputation of any approved drug products we may promote or commercialize.

Modifications to our Consensi drug product or to our oncology therapeutic candidates or any other therapeutic candidate(s) that we may acquire or develop in the future, if approved, will likely require new regulatory approvals before we may continue marketing such product or may require us, or our current or potential development and commercialization partners, as applicable, to recall or cease marketing our Consensi drug product or such therapeutic candidates until approvals are obtained.

Modifications to our Consensi drug product, our oncology therapeutic candidates or any other therapeutic candidate(s) that we may acquire or develop in the future, after they have been approved for marketing, if at all, may require new regulatory approvals, and may result in the recall or suspension of marketing of the product until clearances or approvals of the modified product are obtained. The FDA and other foreign regulatory authorities require manufacturers of approved drugs to make and document a determination of whether or not a modification requires a Prior Approval Supplement, a Changes Being Effected in 30 Days Supplement, or a report in the subsequent Annual Report depending on the impact of the change to the identity, strength, quality, purity, or potency of the approved drug product. A manufacturer may determine in conformity with applicable laws, regulations and guidelines that a modification may be implemented without approval of a Prior Approval Supplement by the FDA or a similar supplement submitted to other foreign regulatory authorities; however, the FDA or other foreign regulatory authorities may disagree with the manufacturer's decision. The FDA or other foreign regulatory authorities may also on their own initiative determine that an approval is required before commencing commercialization of the modified drug product. If the FDA or other foreign regulatory authorities require an approval of any drug product for which we or our current or potential development and commercialization partners previously received marketing approval, we or our current or potential development and commercialization partners may be required to recall such drug product and to stop marketing the drug product as modified, which could require us or our current or potential development and commercialization partners to redesign the therapeutic candidate and cause a material adverse effect on our business, financial condition and results of operations.

CM24 and NT219 may encounter substantial delays in their respective clinical trials or we may not be able to conduct their trials on the timelines we expect.

Clinical testing is expensive, time-consuming, and subject to uncertainty. We cannot guarantee that any CM24, NT219 and/or future drug candidates' clinical studies will be conducted as planned or completed on schedule, if at all. We intend to resume clinical testing of CM24 and continue clinical testing for NT219, but issues may yet arise that could delay or prevent future clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and CM24's or NT219's future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;

- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- the departure of a principal investigator from a clinical site, which could cause delays in conducting the clinical trial at a particular clinical site;
- imposition of a temporary or permanent clinical hold by regulatory agencies;
- delays in recruiting suitable patients to participate in NT219's, CM24's or future drug candidates' clinical studies;
- failure by us or our CROs, or third parties, to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's cGCPs, requirements, or applicable regulatory guidelines in other countries;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of CM24 and NT219 being greater than we anticipate;
- clinical studies of CM24, NT219 and/or future drug candidates producing negative or inconclusive results, which may result in us deciding, or regulators requiring, conduct of additional clinical studies or abandon product development programs; and
- delays in manufacturing, testing, release, validating, or import/export of sufficient stable quantities of CM24, NT219 and/or future drug candidates for use in clinical studies or the inability to do any of the foregoing, including any quality issues associated with contract manufacturers.

In addition, the Coronavirus (COVID-19) pandemic has affected the conduct of clinical trials of investigational therapeutic candidates by causing, among other things, slowdowns in site activities, difficulties or slowdown in patient enrollment, travel limitations, and other limitations for site personnel or trial subjects who became infected with COVID-19, all which has led to difficulties in performing studies. This may lead to difficulties in meeting protocol-specified procedures, including administering or using the therapeutic candidate or adhering to protocol-mandated visits and laboratory/diagnostic testing, unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures, which will likely vary depending on many factors, including the nature of disease under study, the trial design, and in what region(s) the study is being conducted.

We also may conduct clinical research in collaboration with other biotechnology and biologics entities in which we combine CM24 and/or NT219 with the technologies of such collaborators. Such collaborations may be subject to additional delays because of the management of the trials or the necessity of obtaining additional approvals for therapeutics used in the combination trials. These combination therapies will require additional testing and clinical trials will require additional FDA regulatory approval and will increase our future expenses.

Any inability to successfully complete clinical development could result in additional costs to us or impair our ability to generate revenue from our acquisition of CM24. In addition, if we make manufacturing or formulation changes to CM24, we may be required, or may elect, to conduct additional studies to bridge the modified therapeutic candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to commercialize these therapeutic candidates successfully and may harm our business and the results of our operations.

It may take longer and cost more to complete CM24 and/or NT219 clinical trials than initially projected, or we may not be able to complete them at all.

A number of factors, including scheduling conflicts with participating clinicians and clinical institutions, and difficulties in identifying and enrolling patients who meet trial eligibility criteria, may cause significant delays in clinical studies. We may not commence or complete clinical trials involving any of our products as projected or may not conduct them successfully.

We may experience difficulties in patient enrollment in our future clinical trials for a variety of reasons, including as a result of the COVID-19 pandemic. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. In addition, our clinical trials will compete with other clinical trials for therapeutic candidates that are in the same therapeutic areas as our therapeutic candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Accordingly, we cannot guarantee that the trials will progress as planned or as scheduled. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing clinical trial and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our therapeutic candidates.

We expect to rely on medical institutions, academic institutions, or clinical research organizations to conduct, supervise, or monitor some or all aspects of clinical trials involving our products. If we fail to commence or complete, or experience delays in, any of its planned clinical trials, we may experience delays in its clinical development and/or commercialization plans.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- clinicians' and patients' perceptions of the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will not complete a clinical trial; and
- the effect of COVID-19 on the ability of patients to visit the testing sites and the effect of the disease on potential patients who contracted the disease.

Even if we can enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of its therapeutic candidates.

We will depend on a joint collaboration partner to conduct clinical trials with CM24, and we may enter into future collaboration agreements with collaboration partners to develop and conduct clinical trials with, obtain regulatory approvals for, and market and sell the CM24 or other therapeutic candidates. If such collaboration fails to perform as expected, our clinical trials and/or development plans will be delayed and we will be required to seek other collaboration partners, which we may not be able to engage in a timely manner, or at all, and which may delay our development plans and therefore the potential for us to generate future revenue from our therapeutic candidates would be significantly reduced and our business would be significantly harmed.

We have entered into a clinical collaboration agreement with Bristol Myers Squibb Company (NYSE:BMY), for a planned phase 1/2 study of CM24 in combination with a PD-1 antibody nivolumab (Opdivo), and pursuant to an amendment to the agreement we signed on November 4, 2020, we expanded the phase 1/2 clinical trial to also evaluate CM24 and nivolumab, together with nab-paclitaxel (ABRAXANE), in patients with pancreatic cancer. We expect to initiate that study in 2021. We rely, and may in the future continue to rely, on our collaboration partners to develop, conduct clinical trials of, and commercialize our therapeutic candidates and approved products. We may also enter into collaboration agreements with other parties in the future relating to such therapeutic candidates. Ultimately, if such therapeutic candidates are advanced through clinical trials, certain of the collaboration partners may have certain rights in connection with the commercialization of the therapeutic candidate, such as rights of first offer to be responsible for commercialization of these therapeutic candidates. If these collaboration partners do not perform in the manner we expect or fail to fulfill their responsibilities in a timely manner or at all, if the agreements with them terminate or if the quality or accuracy of the clinical data they obtain is compromised, the clinical development, regulatory approval and commercialization efforts related to our therapeutic candidates could be delayed or terminated, and it could become necessary for us to assume the responsibility at our own expense for the clinical development of such therapeutic candidates and seek replacement collaboration and/or development partners. In that event, we would likely be required to limit the size and scope of efforts for the development and commercialization of such product candidate; we would likely be required to seek additional financing to fund further development or identify alternative strategic collaboration partners; our potential to generate future revenue from such therapeutic candidates would be significantly reduced or delayed; and it could have a material adverse effect on our business, financial position, results of operations and future growth prospects.

Collaborations involving our therapeutic candidates pose a number of risks, including the following:

- collaboration partners have significant discretion in determining the efforts and resources that they will apply to these partnerships;
- collaboration partners may have limited supply of products, such as a PD-1 antibody, which we require for the development of our therapeutic candidates;
- collaboration partners may not perform their obligations as expected;
- collaboration partners may not pursue development of our therapeutic candidates or may elect not to continue or renew development programs, based on clinical trial results, changes in the collaboration partners' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaboration partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaboration partners may have or could independently develop, or develop with third parties, products that compete directly or indirectly with our out-licensed therapeutic candidates;

- disagreements with collaboration partners, including disagreements over proprietary rights, contract interpretation or the conduct of product research, development or commercialization programs, may cause delays or lead to termination of such programs, or require us to assume unplanned expenditures, responsibilities or liabilities with respect to therapeutic candidates we have out licensed, or may result in costly and time-consuming litigation or arbitration;

- collaboration partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

- collaboration agreements may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable therapeutic candidates.

In addition, collaboration agreements may provide the collaboration partners with rights to terminate such agreements and licenses granted under such agreements under various conditions, which, if exercised, would adversely affect our product development efforts, could make it difficult for us to attract new collaboration partners and may adversely affect our reputation. A collaboration partner may have the right to terminate its collaboration agreements. Any such termination of any agreement or any future agreement that we may enter into with collaboration partners could have a material adverse effect on our business, financial position and results of operations.

The manufacture of our drug candidates is complex, and we may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities. If we, or any of our third-party manufacturers encounter such difficulties, our ability to supply drugs for clinical trials, or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

NT219 is a chemical and CM24 is a biologic, and the process of manufacturing each is complex, highly regulated and subject to multiple risks. The manufacture of each of NT219 and CM24 involves complex processes, and ultimately infusing such product into a patient. As a result of the complexities, the cost to manufacture biologics such as CM 24 is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Even minor deviations from normal manufacturing processes for each of NT219 and CM24 could result in reduced production yields, product defects, and other supply disruptions.

Developing commercially viable processes is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of raw materials. As a result of these challenges, we may experience delays in NT219's and CM24's clinical development and/or commercialization plans. We may ultimately be unable to reduce the cost of goods for each of NT219 and CM24 to levels that will allow for an attractive return on investment if and when those therapeutic candidates are commercialized.

Because CM24 and NT219 each represents a novel approach to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third-party reimbursement coverage and the commercial potential of CM24 and NT219.

There is no assurance that the approaches offered by CM24 and NT219 will gain broad acceptance among physicians or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for proposed therapeutic candidates. Since CM24 and NT219 each represents new approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these therapeutic candidates. Accordingly, we may spend large amounts of money trying to obtain approval for therapeutic candidates that have an uncertain commercial market. The market for any products that we may successfully develop utilizing CM24 or NT219 will also depend on the cost of the product. We do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture CM24 and NT219, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. Our goal is to reduce the cost of manufacturing CM24 and NT219. However, unless we are able to reduce those costs to an acceptable amount, we may never be able to develop a commercially viable product. If we do not successfully develop and commercialize CM24 and NT219 based upon this approach or find suitable and economical sources for materials used in the production of these therapeutic candidates, the CM24 and NT219 therapeutic candidates will not become profitable.

The CM24 and NT219 therapeutic candidates may be provided to patients in combination with other agents provided by third parties. The cost of such combination therapy may increase the overall cost of CM24 and NT219 based therapy and may result in issues regarding the allocation of reimbursements between our therapeutic candidates and the other agents, all of which may adversely affect the ability to obtain reimbursement coverage for the combination therapy from third-party medical insurers.

If we fail to comply with any obligations under our license agreements, or disputes arise with respect to those agreements, it could have a negative impact on our business and our intellectual property rights.

We are a party to a license agreement with each of Yissum Research and Development Company of the Hebrew University of Jerusalem Ltd. ("Yissum"), the technology transfer company of the Hebrew University of Jerusalem, and Tel Hashomer – Medical Research Infrastructure and Services Ltd. ("THM") that impose, and we may enter into additional licensing arrangements with third parties that may impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Our rights to use the licensed intellectual property are subject to the continuation of and our compliance with the terms of these agreements. Disputes may arise regarding our rights to intellectual property licensed to it from a third party, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the creation or use of intellectual property by us, alone or with its licensors and collaborators;
- the scope and duration of our payment obligations;
- our rights upon termination of such agreement; and
- the scope and duration of exclusivity obligations of each party to the agreement.

If disputes over intellectual property and other rights that we have licensed or acquired from third parties prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected therapeutic candidates. If we fail to comply with our obligations under current or future licensing agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements.

Our shareholders may not realize a benefit from our acquisitions of therapeutic candidates commensurate with the ownership dilution they experienced in connection with the transactions.

If we are unable to realize the strategic and financial benefits anticipated from an acquisition, our shareholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Due to the substantial number of the ADSs (including ADSs issuable upon exercise of the warrants to purchase ADSs) which were issued to shareholders in the acquisitions and the private placements we completed and may complete in the future in order to acquire our therapeutic candidates, the ownership stake and relative voting power of each ordinary share held by our previous shareholders was and may in the future be significantly reduced. Significant management attention and resources will be required to integrate and operate any acquired company. Delays in this process could adversely affect our business, financial results, financial condition and price of our ordinary shares and/or ADSs following any acquisition. Even if we are able to integrate the acquired business operations successfully, there can be no assurance that its integration will result in the realization of the full benefits of synergies, innovation, and operational efficiencies that may be possible from such integration and that the benefits will be achieved within a reasonable period of time.

We may be subject to additional risks because Consensi is a combination of two FDA-approved drugs.

Consensi is comprised of two FDA-approved drugs, celecoxib (the active ingredient in Pfizer's Celebrex) and amlodipine besylate (the active ingredient in Pfizer's Norvasc). Either of these two drugs could independently be found defective or, for a number of other reasons beyond our control, removed from the market and, thus, become unavailable for commercial use as a component of Consensi. Additionally, adverse action of any kind against one of the companies responsible for the drugs of which Consensi is comprised could affect our ability to obtain the applicable drug and/or public perception of us and/or Consensi based on our association with the company at-issue or the use of the applicable drug as a component of Consensi.

If we cannot meet our obligations under our in-license agreement with Yissum, or if other events occur that are not within our control, we could lose our rights to our NT219 therapeutic candidate, experience delays in developing or commercializing our NT219 therapeutic candidate or incur additional costs, which could have a material adverse effect on our business, financial condition and results of operations.

We license rights to our NT219 therapeutic candidate from Yissum pursuant to a license agreement. If we do not meet our obligations under this license agreement, or if other events occur that are not within our control, we could lose the rights to our NT219 therapeutic candidate, experience delays in developing or commercializing our NT219 therapeutic candidate or incur additional costs, any of which could have a material adverse effect on our business, financial condition and results of operations.

We depend on our ability to identify and acquire or in-license therapeutic candidates to achieve commercial success.

We own the rights to FDA-approved drug Consensi which we acquired as a therapeutic candidate in 2013, our NT219 therapeutic candidate which we acquired in 2017, and our CM24 therapeutic candidate which we acquired in 2020, each of which was acquired by us from a third party. We evaluate internally and with external consultants each potential therapeutic candidate. However, there can be no assurance as to our ability to accurately or consistently select therapeutic candidates that have the highest likelihood to achieve commercial success.

The recent coronavirus outbreak may adversely affect our revenues, results of operations and financial condition.

In December 2019, a strain of coronavirus (COVID-19) surfaced in Wuhan, China, and in March 2020, the World Health Organization declared COVID-19 a pandemic and recommended containment and mitigation measures worldwide. COVID-19 has subsequently reached multiple countries, resulting in government-imposed quarantines, travel restrictions and other public health safety measures worldwide, including Israel. The various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 have had an adverse effect on the global markets and global economy, including on the availability and pricing of resources, materials, manufacturing and delivery efforts and other aspects of the global economy. The Israeli Ministry of Health has implemented various outbound travel restrictions, inbound quarantine requirements for passengers arriving from certain countries and/or events in other countries, including not allowing certain foreign nationals to disembark in Israel, as well as ordering curtailment of public gatherings, trade and other activities within Israel.

The impact of the COVID-19 pandemic on the conduct of clinical trials of our therapeutic candidates, and the challenges that have arisen, for example, from quarantines, travel limitations, and other considerations from site personnel or trial subjects becoming infected with COVID-19, have led to a slowdown of clinical trials (and slowed patient enrollment in the trials that we have conducted) and development activities. The impact of the pandemic may also lead to difficulties in meeting protocol-specified procedures, including administering or using the therapeutic candidate or adhering to protocol-mandated visits and laboratory/diagnostic testing, unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures, which will likely vary depending on many factors, including the nature of disease under study, the trial design, and in what region (s) the study is being conducted.

The COVID-19 pandemic may in the future disrupt production and cause delays in the supply and delivery of products used in our operations, affect our operations (including the conduct of clinical studies), the ability of regulatory bodies to grant approval, review our submissions or supervise our candidates and products, divert the attention and efforts of the medical community to coping with COVID-19 and disrupt the marketplace in which we operate, and may have a material adverse effects on our operations.

While the COVID-19 pandemic has not materially affected our operations to date, the extent to which the COVID-19 pandemic shall impact our operations will depend on future developments. In particular, the continued spread of COVID-19 globally could materially adversely impact our operations and workforce, including our manufacturing activities, clinical trials and product sales, including the commercialization of Consensi, as well as our ability to continue to raise capital.

Our business could suffer if we are unable to attract and retain key employees.

The loss of the services of members of senior management or other key personnel could delay or otherwise adversely impact the successful completion of our planned CMC, research and development, preclinical studies and/or clinical trials or the commercialization of our therapeutic candidates or otherwise affect our ability to manage our company effectively and to carry out our business plan. We do not maintain key-man life insurance for any of our personnel. Although we have entered into employment or consultancy agreements with all of the members of our senior management team, members of our senior management team may resign at any time. High demand exists for senior management and other key personnel in the pharmaceutical industry. There can be no assurance that we will be able to continue to retain and attract such personnel.

Our growth and success also depend on our ability to attract and retain additional highly qualified scientific, technical, business development, marketing, managerial and finance personnel. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to liability from their former employers. In addition, if we elect to independently commercialize any therapeutic candidate, we will need to expand our marketing and sales capabilities. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel. Compensation packages for our senior officers are subject to approval of our compensation committee and board of directors and, in certain instances, our shareholders as well. We may not be able to achieve the required corporate approvals for proposed compensation packages, further making it difficult for us to compete successfully with other companies in order to attract and retain key personnel. If we cannot attract and retain sufficiently qualified technical employees on acceptable terms, we may not be able to develop and commercialize competitive therapeutic candidates. Further, any failure to effectively integrate new personnel could prevent our business from successfully growing.

We are an international business, and we are exposed to various global and local risks that could have an adverse effect on our business.

We operate our business in multiple international jurisdictions. Such operations could be affected by changes in foreign exchange rates, capital and exchange controls, travel restrictions, public health restrictions, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, trade regulations and procedures and actions affecting approval, production, pricing, and marketing of, reimbursement for and access to, our products, as well as by political unrest, unstable governments and legal systems and inter-governmental disputes. Any of these changes could adversely affect our business.

The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drug candidate, Consensi.

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes in the future. There is uncertainty as to the regulatory approach in China with respect to combination drug products. Any such uncertainty, changes or amendments may cause delays in or prevent the market authorization or the successful commercialization of our Consensi drug product in China and reduce the current benefits we believe are available to us from our commercialization agreement with Hebei Changshan Biochemical Pharmaceutical Co., Ltd. (Changshan Pharma). Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by Changshan Pharma to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may prevent the receipt of market authorization for Consensi in China or otherwise result in the suspension of the commercialization of Consensi in China.

Changes in the political and economic policies of the Chinese government may materially and adversely affect the commercialization of Consensi in China.

The Chinese economy differs from the economies of most developed countries in many respects, including the extent of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the government. In addition, the Chinese government continues to play a significant role in regulating industrial development by imposing industrial policies. The Chinese government also exercises significant control over China's economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, regulating financial services and institutions and providing preferential treatment to particular industries or companies.

While the Chinese economy has experienced significant growth in the past three decades, growth has been uneven, both geographically and among various sectors of the economy. The Chinese government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy but may also have a negative effect on us and our products. For example, our commercialization of Consensi in China could be materially and adversely affected by government control over capital investments, changes in tax regulations, or as of yet unknown impacts of the coronavirus outbreak.

Our subsidiary, TyrNovo, has received and may continue to receive Israeli governmental grants to assist in the funding of its research and development activities.

Our subsidiary, TyrNovo, has obligations to the Israel Innovation Authority, or IIA (formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry) with respect to grants it received from the IIA connection with NT219 and other TyrNovo's technology, in an aggregate amount of approximately NIS 5.5 million (or approximately $1.71 million). The requirements and restrictions for such grants are set forth in the Encouragement of Research, Development and Technological Innovation in Industry Law, 5744-1984 (formerly known as the Law for the Encouragement of Research and Development in Industry, 5744-1984), or the Innovation Law, the IIA's rules and guidelines and the terms of these grants.

In general, the recipients of grants, or Recipient Company(ies), are obligated to pay the IIA royalties from the revenues generated from the sale of products and related services developed in whole or in part as a result of a research and development program funded by the IIA at rates which are determined under the IIA's rules and guidelines (generally of 3% to 5% on sales of products or services developed under the approved programs, depending on the type of the Recipient Company, which rates may be increased under certain circumstances) up to the aggregate amount of the total grants received by the IIA which may be increased under certain circumstances, as described below), plus annual interest (as determined in the IIA's rules and guidelines).

TyrNovo's technologies, including NT219, were developed, at least in part, with funds from IIA grants, and accordingly TyrNovo is obligated to pay royalties on sales of any of its IIA funded products and related services. In addition, the Government of Israel may, from time to time, audit sales of products which it claims incorporate technology and know-how funded via IIA programs and this may lead to additional royalties being payable on additional products. As of December 31, 2020, the maximum royalty amount that would be payable by TyrNovo, excluding interest, is approximately NIS 5.5 million ($1.71 million), and as of such date TyrNovo had not paid any royalties to the IIA.

Following the full payment of such royalties and interest, there is generally no further liability for royalty payments; however, other restrictions under the Innovation Law continue to apply.

The IIA grants which TyrNovo's technology, including NT219, has received for research and development expenditures restrict its ability to manufacture products and transfer (including by way of license for R&D purposes) know-how outside of Israel and require it to satisfy specified conditions. In addition, we may encounter difficulties partnering TyrNovo's therapeutic candidates with entities outside of Israel due to certain restrictions regarding manufacturing and transferring of know-how (including by a way of license for R&D purposes) outside of Israel imposed due to the receipt of the IIA grants.

The research and development efforts underlying TyrNovo's technology including NT219 have been financed, in part, through the grants received from the IIA. TyrNovo, therefore, must comply with the requirements of the Innovation Law and the IIA's rules and guidelines.

Under the IIA's rules and guidelines, TyrNovo is generally prohibited from manufacturing products developed using the IIA funding outside of the State of Israel without the prior approval of the IIA (except for the transfer of less than 10% of the manufacturing capacity in the aggregate which requires only a notice) and subject to payment of increased royalties (up to 300% of the grant amount plus accrued interest, depending on the manufacturing volume that is performed outside of Israel). TyrNovo may not receive the required approvals for any proposed transfer of manufacturing activities. This restriction may impair TyrNovo's ability to outsource manufacturing rights abroad.

Additionally, under the IIA's rules and guidelines, TyrNovo is prohibited from transferring the IIA-funded know-how and related intellectual property rights outside of the State of Israel, except under limited circumstances and only with the prior approval of the IIA. TyrNovo may not receive the required approvals for any proposed transfer, and even if received, TyrNovo may be required to pay the IIA a redemption fee of up to 600% of the grant amounts plus accrued interest.

Approval of the transfer of know-how to an Israeli company is required, and may be granted if the recipient assumes all of our responsibilities towards the IIA including the restrictions on the transfer of know-how and the manufacturing rights outside of Israel and the obligation to pay royalties, and, although such transfer will not be subject to the payment of a redemption fee, there will be an obligation to pay royalties to the IIA from the income of such sale transaction as part of the royalty payment obligation. No assurance can be given that approval to any such transfer, if requested, will be granted.

These restrictions may impair our ability to perform or outsource manufacturing outside of Israel, or otherwise transfer or sell TyrNovo's IIA funded know-how outside of Israel. It may also require TyrNovo to obtain the approval of the IIA for certain actions and transactions and pay additional royalties and other amounts to the IIA. Furthermore, the consideration available to TyrNovo's and/or our shareholders in a transaction involving the transfer outside of Israel of know-how developed with IIA funding (such as a merger or similar transaction) may be reduced by any amounts that TyrNovo is required to pay to the IIA. If TyrNovo fails to comply with the requirements of the Innovation Law and the IIA's rules and guidelines, TyrNovo may be required to return certain grants previously received along with interest and penalties and may become subject to criminal proceedings.

Risks Related to Our Industry

Even though Consensi received regulatory approval in the United States and even if our oncology therapeutic candidates or any other therapeutic candidate that we develop in the future receive regulatory approval or do not require regulatory approval, they may not become or remain commercially viable products.

Even though Consensi is approved by the FDA for marketing in the United States, it may not be a commercially viable product that is accepted by physicians and patients in the United States. Even though we believe that the FDA approved Consensi for a commercially viable purpose in the simultaneous treatment of pain caused by osteoarthritis and hypertension, we cannot predict whether the FDA may limit the use of Consensi to treatments that are not commercially viable, which would severely affect our operations and revenue.

Likewise, even if our oncology therapeutic candidates and/or any other therapeutic candidate that we may develop or acquire in the future are approved for commercialization by the FDA or a foreign authority in the future, they may not be commercially viable products. For example, if we or our potential commercialization partners receive regulatory approval to market a therapeutic candidate, approval may be subject to limitations on the indicated uses or subject to labeling or marketing restrictions which could materially and adversely affect the marketability and profitability of the therapeutic candidate. In addition, a new therapeutic candidate may appear promising at an early stage of development or after preclinical studies and/or clinical trials but never reach the market, or it may reach the market but not result in sufficient product sales, if any. A therapeutic candidate may not result in commercial success for various reasons, including:

- difficulty in large-scale manufacturing, including yield and quality;
- low market acceptance by physicians, healthcare payers, patients and the medical community as a result of lower demonstrated clinical safety or efficacy compared to other products, prevalence and severity of adverse side effects, or other potential disadvantages relative to alternative treatment methods;
- insufficient or unfavorable levels of reimbursement from government or third-party payers, such as insurance companies, health maintenance organizations and other health plan administrators;
- infringement on proprietary rights of others for which we or our potential commercialization partners have not received licenses;
- incompatibility with other therapeutic candidates;
- other potential advantages of alternative treatment methods and competitive forces that may make it more difficult for us to penetrate a particular market segment;
- ineffective marketing and distribution support;
- lack of significant competitive advantages over existing products on the market;
- lack of cost-effectiveness; or
- timing of market introduction of competitive products.

Physicians, various other health care providers, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend Consensi, our oncology therapeutic candidates or any other therapeutic candidates that we may develop or acquire in the future. If we are unable, either on our own or through third parties, to manufacture, commercialize and market such products when planned, or develop or acquire commercially viable therapeutic candidates, we may not achieve any market acceptance or generate revenue.

The markets for our Consensi drug product and our oncology therapeutic candidates are rapidly changing and competitive, and new drug delivery mechanisms, drug delivery technologies, new drugs and new treatments which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The pharmaceutical and biotechnology industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address the indications treated by Consensi and for which we are currently developing our other oncology therapeutic candidates. There are various other companies that currently market or are in the process of developing products that address all of the indications or diseases treated by our Consensi drug product or our therapeutic candidates.

New drug delivery mechanisms, drug delivery technologies, new drugs and new treatments that have been developed or that are in the process of being developed by others may render our Consensi drug product or our oncology therapeutic candidates noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Some of these technologies may have an entirely different platform or means of treating the same indications as Consensi, NT219, CM24 or other therapeutic candidates that we may develop in the future. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities, human resources and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

For example, since 2010, the opioid epidemic in the United States has increasingly been recognized as a major cause of death. The CDC estimates that from 2010 to 2016 over 600,000 Americans died from opioid overdoses, and that in 2017, this number reached 70,237. As a result, individuals, corporations, and the FDA have increasingly sought to decrease the over utilization of opioids. One method for decreasing the use of opioids is to increase the use of other analgesics. We believe that Consensi could potentially replace opioids for many types of chronic pain. However, it is possible that new drugs and new treatments that have been developed or that are in the process of being developed by others in order to reduce the use of opioids may render Consensi noncompetitive in this market.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our formulations or therapeutic candidates, even if commercialized. Many of our targeted diseases and conditions can also be treated by other medications or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our Consensi drug product or our therapeutic candidates to receive widespread acceptance.

If third-party payers do not adequately reimburse customers for our Consensi drug product, or our oncology therapeutic candidates, if approved, or any of other therapeutic candidates that may be approved for marketing in the future, they might not be purchased or used, and our revenues and profits will not develop or increase.

Our revenues and profits will depend heavily upon the availability of adequate coverage and reimbursement for the use of our Consensi drug product that is approved for commercialization, and of our oncology therapeutic candidates, if approved, or any of other therapeutic candidates that may be approved for marketing in the future, if at all, from governmental and/or other third-party payers, both in the U.S. and in foreign markets. Our Consensi drug product has not yet received reimbursement from all government or other third party payers. There may be significant delays in obtaining coverage for newly approved therapeutic candidates. Moreover, eligibility for coverage does not necessarily signify that an approved product will be reimbursed in all cases or at a sufficient rate, including one that covers our costs, such as research, development, manufacture, sale, and distribution costs. Accordingly, even if we succeed in bringing one or more of our therapeutic candidates to the market, they may not be considered cost-effective, and the amount reimbursed may be insufficient to allow us to sell our approved products on a competitive basis. Reimbursement by a third-party payer may depend upon a number of factors, including the third-party payer's determination that the use of an approved product is, among others:

- a covered benefit under its health plan;
- safe, effective and medically necessary;

- appropriate for the specific patient;
- cost-effective, including compared to approved alternate therapies; and
- neither experimental nor investigational.

Obtaining reimbursement approval for an approved product from each government or other third-party payer is a time-consuming and costly process that could require us or our current or potential development and commercialization partners to provide supporting scientific, clinical and cost-effectiveness data for the use of an approved product to each payer. Even when a payer determines that an approved product is eligible for reimbursement, the payer may impose coverage limitations that preclude or restrict payment for some uses that are approved by the FDA or other foreign regulatory authorities. Reimbursement rates may vary according to the use of the approved product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints or imperfections in Medicare, Medicaid or other data used to calculate these rates.

Increasingly, the third-party payers who reimburse patients or healthcare providers, such as government and private insurance plans, are seeking greater upfront discounts, additional rebates, and other concessions to reduce the prices for approved products. If the price we are able to charge for any approved product, or the reimbursement provided for such approved product, is inadequate or becomes inadequate in light of our development and other costs, our return on investment could be adversely affected.

It has been reported that generic drug prices have generally fallen in the past few years. When this has occurred, profits of certain generic drug companies, such as Teva Pharmaceuticals (NYSE:TEVA; TASE:TEVA), have also generally fallen. With the decrease in profits, the stock prices of publicly traded generic pharmaceutical companies have in the past often fallen in tandem. It is unclear to us what effect this might have on the marketing of Consensi which, while patented, is comprised of two separate generic drug components.

In the U.S., there have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services which may affect payments for our Consensi drug product in the U.S. or our oncology therapeutic candidates, if approved. We believe that legislation that reduces reimbursement for our Consensi drug product or our oncology therapeutic candidates, if approved, could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our Consensi drug product, or our oncology therapeutic candidates, if approved. This could materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our Consensi drug product, or our oncology therapeutic candidates, if approved. At this stage, we are unable to estimate the extent of the direct or indirect impact of any such federal and state proposals.

Further, coverage and reimbursement policies are subject to change and are not always consistent across different payers or even federal healthcare programs. For example, the Centers for Medicare and Medicaid Services (CMS) frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values which may be revised or interpreted in ways that could significantly affect our business and products. Government and private third-party payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Moreover, both CMS and other third-party payers may have sufficient market power to demand significant price reductions. Such price reductions and/or other significant coverage policies or payment limitations could materially and adversely affect our business, financial condition and results of operations.

Legislative or regulatory reform of the healthcare system in the United States may harm our business.

A number of legislative and regulatory changes in the healthcare system in the U.S. have been proposed and adopted in recent years, and efforts of the legislature and third-party payers to contain or reduce the cost of healthcare and broaden the availability of healthcare continue. These developments could, directly or indirectly, affect our ability to sell our Consensi drug product or our oncology therapeutic candidates, if approved, in the U.S. On March 23, 2010, the Patient Protection and Affordable Care Act (P.L. 111-148) was signed into law, followed by the Health Care and Education Reconciliation Act (P.L. 111-152) on March 30, 2010 (referred to, collectively, as the "Healthcare Reform Law"). The Healthcare Reform Law was enacted with the intent to broaden access to health insurance, reduce or constrain the growth of health spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare industry, impose new taxes and fees, and impose additional policy reforms, among others. In addition, the Healthcare Reform Law included a number of new rules regarding health insurance, the provision of healthcare, and conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients and other healthcare policy reforms, largely designed to encourage providers to find cost savings in their clinical operations.

The Healthcare Reform Law sparked one of the most comprehensive and significant reforms in the history of the U.S. healthcare industry, has significantly changed the way healthcare is financed and has impacted the scope of healthcare insurance and incentives, among others. Pharmaceuticals represent a significant portion of the cost of providing healthcare. The environment created by the Healthcare Reform Law has caused changes in the purchasing habits of consumers and providers and resulted in specific attention to the pricing negotiation, product selection and utilization review in relation to pharmaceuticals. This attention may result in our Consensi drug product or our oncology therapeutic candidates, if approved, being chosen less frequently or the pricing being substantially lowered.

Certain facets of the Healthcare Reform Law and subsequent legislation, such as the extension of medical benefits to those who previously lacked coverage may, in the long term, result in substantial costs to the U.S. government, which may force significant additional changes to the U.S. healthcare system. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care and increased enforcement activities. Cost of care could be reduced further by decreasing the level of reimbursement for medical services or products (including our Consensi drug product or those oncology therapeutic candidates currently being developed by us or our development or commercialization partners, if approved), or by restricting coverage (and, thereby, utilization) of medical services or products. Continued restructuring of medical care coverage in the U.S. could further impact the reimbursement for the types of prescribed drugs and pharmaceuticals that we and our development or commercialization partners are developing. If reimbursement or utilization for our Consensi drug product or our oncology therapeutic candidates (if approved) is substantially reduced or otherwise adversely affected in the future, or rebate or similar obligations or fees associates with them are imposed or substantially increased, it could have a material adverse effect on our business, financial condition and results of operations.

Further, the U.S. healthcare environment has seen significant changes in recent years and is still in flux. Judicial challenges as well as legislative initiatives to modify, limit, or repeal the Healthcare Reform Law have been initiated and continue to evolve. For example, former President Trump issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Healthcare Reform Law and in which he directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the Healthcare Reform Law to the maximum extent permitted by law. Congress has enacted legislation that repeals certain portions of the Healthcare Reform Law, including but not limited to the Tax Cuts and Jobs Act, passed in December 2017, which included a provision that eliminates the penalty under the Healthcare Reform Law's individual mandate, effective January 1, 2019, as well as the Bipartisan Budget Act of 2018, passed in February 2018, which, among other things, increases pharmaceutical manufacturers' discount in the Coverage Gap Discount Program from 50% to 70% of the negotiated price of applicable drugs.

Additionally, in December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the Healthcare Reform Law is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the Healthcare Reform Law. Substantial uncertainty remains as to the future of the Healthcare Reform Law as the case was appealed to the U.S. Supreme Court and currently awaiting a ruling. It is unknown whether, and to what extent, if any, the Healthcare Reform Law will remain in-effect in the future, and it is unclear how judicial decisions, subsequent appeals, legislative or executive measures, or other efforts to repeal and replace or, possibly, to restore the Healthcare Reform Law will impact the U.S. healthcare industry or our business.

We are subject to additional federal and state healthcare laws and regulations relating to our business, and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

Healthcare providers, physicians, and third-party payers play a primary role in the recommendation and prescription of our Consensi drug product and any therapeutic candidates for which we obtain marketing approval. Our current or future arrangements with healthcare providers, physicians, marketers or sales personnel, third-party payers, patients, and others in a position to refer, recommend, purchase, or use our products may expose us to broadly applicable U.S. federal and state fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our approved products. The laws that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;

- the federal Anti-Inducement Law (also known as the Civil Monetary Penalties Law), which prohibits a person from offering or transferring remuneration to a Medicare or State healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program;

- the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients for certain designated health services where that physician or family member has a financial relationship with the entity providing the designated health service, unless an exception applies;

- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;

- the so-called federal "Sunshine Act", which requires certain pharmaceutical and medical device companies to monitor and report certain payments and other transfers of value to physicians and teaching hospitals and ownership or investment interests held by physicians or their immediate family members to CMS for disclosure to the public;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations, which impose obligations on certain covered entities and their business associates with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals, regulatory authorities, and potentially the media of certain breaches of security of individually identifiable health information;

- HIPAA's fraud and abuse provisions, which impose criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulate drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use, and regulates the distribution of samples;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and

- state law equivalents of each of the above federal laws, such as anti-kickback, false claims, transparency and reporting laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, many of which differ from each other in significant ways, thus complicating compliance efforts.

Compliance efforts may involve substantial costs and resources, and if our operations or business arrangements are found to be in violation of any such requirements, we may be subject to penalties, including civil or criminal penalties, monetary damages, the curtailment or restructuring of our operations, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful.

Most recently, there has been a trend in federal and state legislation aimed at lowering costs for drug products, including by requiring pharmaceutical companies to disclose information about their pricing and production and marketing costs, and heightened governmental scrutiny over the manner in which pharmaceutical manufacturers set prices for their marketed products. There have been several presidential executive orders and U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, on October 10, 2018 the Patient Right to Know Drug Prices Act (for private plans) and the Know the Lowest Price Act (for Medicare Parts C and D) were signed into law, which prohibited health plans from restricting pharmacies from informing individuals regarding prices for certain drugs. On November 20, 2020, the U.S. Department of Health and Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed in response to ongoing litigation. In addition, in November 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. Given resulting litigation and preliminary injunctions that were issued, the rule was not implemented and will not be implemented without further rulemaking. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. For example, in June 2016 Vermont became the first state to pass legislation requiring certain drug companies to disclose information relating to justification of certain price increases, and many other states have since followed suit. These efforts and any other such legislation requiring publication of drug costs could materially and adversely impact our business, financial condition, and results of operations by promoting a reduction in drug prices or encouraging purchasers to use other low-cost, established drugs or therapies.

In addition, there has been a trend of increased federal and state regulation of payments made to physicians or others in a position to refer, purchase, or recommend drug products. For example, some states impose a legal obligation on companies to adhere to voluntary industry codes of behavior (e.g., the PhRMA Code), which apply to pharmaceutical companies' interactions with healthcare providers, some mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians, and some states limit or prohibit such gifts. Further, the Healthcare Reform Law, among other things, amended the intent requirement of the federal Anti-Kickback Statute so that a person or entity can now be found guilty of fraud or an anti-kickback violation without actual knowledge of the statute or specific intent to violate it. In addition, the Healthcare Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statue constitutes a false or fraudulent claim for purposes of the False Claims Act.

The scope and enforcement of these laws are broad, often uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and guidance in many areas. We cannot predict the impact that new legislation or any changes in existing legislation will have on our business, financial condition, or results of operations. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations, and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming and could negatively and adversely affect our business and results of operations.

We could be exposed to significant drug product liability claims, which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage.

The clinical trials that we conduct, conducted or may have to conduct, and the testing, manufacturing, marketing and commercial sale of our Consensi drug product, or our oncology therapeutic candidates or any other therapeutic candidates that we may develop or acquire in the future, involve and will involve an inherent risk that significant liability claims may be asserted against us. Should we decide to seek additional insurance against such risks before we initiate clinical trials or commence our product sales, there is a risk that such insurance will be unavailable to us, or if it can be obtained at such time, that it will be available only at an unaffordable cost. Even if we obtain insurance, it may prove inadequate to cover claims or litigation costs, especially in the case of wrongful death claims. Product liability claims or other claims related to our Consensi drug product, or our therapeutic candidates or any other therapeutic candidate that we may develop or acquire in the future, regardless of their outcome and merit, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our Consensi drug product, or our therapeutic candidates or any other therapeutic candidates that we may develop or acquire in the future. A product liability claim could also significantly harm our reputation and delay market acceptance of our Consensi drug product, or our therapeutic candidates or any other therapeutic candidate that we may develop or acquire in the future.

Our business involves risks related to handling regulated substances which could severely affect our ability to conduct research and development of our therapeutic candidates.

In connection with our current or potential development and commercialization partners' research and clinical development activities, as well as the manufacture of materials and therapeutic candidates, we and our current or potential development and commercialization partners are subject to foreign, federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. We and our current or potential development and commercialization partners may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and clinical development, as well as the activities of our manufacturing and current or potential development and commercialization partners, both now and in the future, may involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals. We cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

Risks Related to Legal Proceedings and Intellectual Property

Legal proceedings or third-party claims of intellectual property infringement and other legal challenges may require us to spend substantial time and money and could prevent us from or delay us in developing or commercializing our therapeutic candidates. An adverse result in any infringement claim or other legal challenges could have a material adverse effect on our business, results of operations and financial condition.

The development, manufacture, use, offer for sale, sale or importation of our therapeutic candidates may infringe on the claims of third-party patents or other intellectual property rights. The nature of claims contained in unpublished patent filings around the world is unknown to us, and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. We may also be subject to claims based on the actions of employees and consultants with respect to the usage or disclosure of intellectual property learned at other employers. The cost to us of any intellectual property litigation or other infringement 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 because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of intellectual property litigation or other legal proceedings or litigation could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant cash resources and management time. Consequently, we are unable to guarantee that we will be able to manufacture, use, offer for sale, sell or import our therapeutic candidates in the event of an infringement action.

In the event of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a therapeutic candidate or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement or other claims, we are unable to enter into licenses on acceptable terms.

On December 21, 2020, Bar Ilan University and BIRAD Research & Development Company Ltd. (the "University" and "BIRAD", respectively) filed a statement of claim to the court against TyrNovo, the Company, its officers and others. In the claim, the petitioners allege that the University is the rightful owner of a patent owned by TyrNovo. The main remedy sought by the petitioners is a declaratory relief under which the University is declared the owner of such patent. We plan to file our response in April 2021, when it is due. At this preliminary stage we are unable, with any degree of certainty, to make any evaluations or any assessments with respect to the probability of success or the scope of potential exposure, if any.

On August 4, 2020, Lupin Ltd. and Lupin Pharmaceuticals USA, Inc. (together, "Lupin") notified Purple and Coeptis Pharmaceuticals, Inc. ("Coeptis"), our distribution partner for Consensi, that it had filed an Abbreviated New Drug Application ("ANDA") with the FDA to market a generic version of Consensi. Lupin also sent both parties a Paragraph IV Notice Letter alleging that certain of our patents are invalid and/or not infringed by Lupin's proposed generic product. In September 2020, we filed a complaint in the United States District Court for the District of New Jersey against Lupin and claimed that Lupin's proposed generic product infringes certain of our patents and sought declaratory and injunctive relief. On January 12, 2021, the court issued an order providing a schedule for the briefs and other items to be submitted, and the discovery to be conducted, by the parties, which will take place over the course of 2021.

From time to time, we may also be involved in various lawsuits and legal proceedings other than intellectual property infringement actions, concerning such laws as corporate and securities laws, business laws, product liability laws, and environmental laws. On December 3, 2015, we announced that we received a lawsuit and motion to approve the lawsuit as a class action lawsuit pursuant to the Class Action Lawsuits Law 5766-2006 which was filed against us and our directors at the Tel Aviv District Court (Economic Division). The motion asserts claims for damages to the holders of our securities listed on the TASE, arising due to the initial public offering of our securities in the U.S. during November 2015. A separate, similar claim in the amount of NIS 1.1 million was filed against us in May 2018 by an individual shareholder seeking to separate from the purported class in the original motion. Additionally, on February 16, 2017, we announced that four lawsuits and motions to approve the lawsuits as a class action lawsuit (one of which was later withdrawn, and the remainder of which were later consolidated into one motion) were filed against us and certain of our office holders in the Tel Aviv District Court (Economic Division), and served on us, with each such motion relating to the former investigation by the Israel Securities Authority ("ISA") into certain of our public disclosures (all of the motions above collectively, the "Israel Motions").

In addition, in February 2017 class actions lawsuits largely relating to the same matters were filed in the State of California and in the U.S. district court for the Southern District of New York against us, our CEO and former CFO, and in the California lawsuits, against the underwriters of our November 2015 initial public offering in the U.S.A. (collectively, the "US Motions"). We finalized a settlement agreement with respect to the US Motions, which was approved by the court on March 22, 2019. Under the terms of the settlement, the classes in all of the actions received aggregate consideration of $2.0 million (the "US Settlement"), all of which, as well as ancillary expenses, were funded by our insurance carriers. Pursuant to the US Settlement, we and our directors and officers as well as the other defendants named in the actions were released from the claims that were asserted or could have been asserted in the actions by class members participating in the settlement. The US Settlement contains no admission of wrongdoing and reiterates that we have always maintained and continue to believe that we did not engage in any wrongdoing or otherwise commit any violation of federal or state securities laws or other laws.

In Israel, we were previously subject to a formal investigation by the ISA (the "ISA Investigation") into our public disclosures around certain aspects of the studies related to our therapeutic candidate, Consensi. On August 13, 2019, the Administrative Enforcement Committee (the "Committee") of the ISA approved an administrative enforcement agreement, titled Enforcement Arrangement ("Enforcement Arrangement"), entered into by and amongst the ISA, Purple Biotech, Isaac Israel, our chief executive officer, Dr. Paul Waymack, our former chairman and Simcha Rock, our former chief financial officer and currently a director, pursuant to which the Company and each of Messrs. Israel, Waymack and Rock settled the ISA's claims that under Israeli Securities Laws the Company made negligent disclosures in a number of its historical reports filed with the ISA in 2014 and 2015, and the ISA decided to discontinue its criminal investigation and to cease all proceedings us and our principals. As part of the Enforcement Arrangement, the Company agreed to pay a fine of NIS 1,500,000 (approximately $430,000), payable in 24 consecutive monthly payments, of which $322,500 has been paid to date, and the different principals agreed to each pay a fine. Messrs. Israel and Rock each also agreed to be subject to a conditional prohibition to serve as a senior officer in a supervised body under the Israeli Securities Law for a period of 12 months in the event that he violates certain sections under the Israeli securities laws within two years.

While we do not expect the Enforcement Arrangement to have a material impact on the Company's statement of operations, we do not yet know to what extent it may have an impact on the proceedings being conducted under the Israel Motions which are still continuing at the Tel Aviv District Court. In addition, the ongoing proceedings described above could result in significant legal defense costs and high punitive damage payments. Although we maintain directors' and officers' liability insurance (with an extension to cover the Company as well) and which is expected to cover much of our expected costs (legal and otherwise) in connection with the ongoing lawsuits and outstanding payments described above, after payment by us of the policy deductibles, the insurance companies may reject our claims for coverage under the policy or the coverage may not be adequate to cover future claims. Furthermore, we were required to indemnify our underwriters for their legal defense costs or any other damages in the California lawsuits, and such indemnification was not covered under the policy. We paid our underwriters to indemnify them for their legal costs in connection with the California lawsuits an aggregate amount of approximately $186,900.

Additionally, we may be unable to maintain our existing directors' and officers' liability insurance in the future at satisfactory rates or adequate coverage amounts and may incur significant increases in insurance costs.

It is difficult to foresee the results of legal actions and proceedings currently involving us or those which may arise in the future, and an adverse result in these matters could have a material adverse effect on our business, results of operations and financial condition. In addition, any legal or administrative proceedings which we are subject to could require the significant involvement of our senior management and may divert management attention from our business and operations.

We may be unable to adequately protect or enforce our rights to intellectual property, causing us to lose valuable rights. Loss of patent rights may lead us to lose market share and potential profits.

Our success depends, in part, on our ability, and the ability of our current or potential development and commercialization partners to obtain patent protection for our therapeutic candidates, maintain the confidentiality of our trade secrets and know-how, operate without infringing on the proprietary rights of others and prevent others from infringing our proprietary rights.

We try to protect our proprietary position by, among other things, filing U.S. and other patent applications related to our therapeutic candidates, inventions and improvements that may be important to the continuing development of our therapeutic candidates.

Because the patent position of pharmaceutical companies involves complex legal and factual questions, we cannot predict the validity and enforceability of any patents we may obtain with certainty. Our competitors may independently develop drug delivery technologies or products similar to ours or design around or otherwise circumvent any patents that may be issued to or licensed by us. Our pending patent applications, and those that we may file in the future or those we may license from third parties may not result in patents being issued. If these patents are issued, they may not provide us with proprietary protection or competitive advantages. The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

Patent rights are territorial; thus, the patent protection we have sought will only extend, if issued, to those countries, if any, in which we will be issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the U.S. Competitors may successfully challenge any of our patents, produce similar drugs or products that do not infringe such patents, or produce drugs in countries where we have not applied for patent protection or that do not respect such patents. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

After the completion of development and registration of any future patents, third parties may still act to manufacture or market our therapeutic candidates in infringement of our patent protected rights. Such manufacture or marketing of our therapeutic candidates in infringement of any patent-protected rights is likely to cause us damage and lead to a reduction in the prices of our therapeutic candidates, thereby reducing our potential profits.

We may invest a significant amount of time and expense in the development of our therapeutic candidates only to be subject to significant delay and patent litigation before they may be commercialized. In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our therapeutic candidates, any patents that may be issued that protect our therapeutic candidates 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 generic products into the market and a subsequent decline in market share and profits.

We are developing some of our therapeutic candidates in collaboration with academic and other research institutes. While we attempt to ensure that our intellectual property is protected under the terms of our collaboration agreements with such institutes, these institutes may have claims to our intellectual property.

We do not have patent protection in certain countries, and we may not be able to effectively enforce our intellectual property rights in certain countries, which could significantly erode the market for our product candidates.

We are seeking or intend to seek regulatory approval to market Consensi or our therapeutic candidates in a number of foreign countries, including China and South Korea. Consensi and our therapeutic candidates are not protected by patents in certain countries, including China where we are currently seeking patent protection and South Korea, which means that competitors may be free to sell products that incorporate the same technology that is used in our products in those countries. In addition, the laws and practices in some foreign countries may not protect intellectual property rights to the same extent as in the United States. We or our licensors may not be able to effectively obtain, maintain or enforce rights with respect to the intellectual property relating to our product candidates in those countries. In that regard, we believe that although China is one of the largest potential markets for some of our products under development, some of our product candidates are not protected by patents in China and it may be difficult to enforce intellectual property rights in China. Our lack of patent protection in one or more countries, or the inability to obtain, maintain or enforce intellectual property rights in one or more countries, could adversely affect our ability to commercialize our products in those countries and could otherwise have a material adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

In addition to filing patents, we generally try to protect our trade secrets, know-how and technology by entering into confidentiality or non-disclosure agreements with parties that have access to it, such as our current or potential development and commercialization partners, employees, contractors and consultants. We also enter into agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees, advisors, research collaborators, contractors and consultants while we employ or engage them. However, these agreements can be difficult and costly to enforce or may not provide adequate remedies. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor. In addition, monitoring infringement of intellectual property rights is difficult, and we cannot be certain that the steps we have taken will prevent unauthorized use of our know-how, particularly in China and other countries in which the laws may not protect our proprietary rights as fully as the laws of the United States. Accordingly, other parties, including competitors, may improperly duplicate our products using our proprietary technologies. Pursuing legal remedies against persons infringing our patents or otherwise improperly using our proprietary information is a costly and time-consuming process that would divert management's attention and other resources from the conduct of our normal business.

To the extent that any of our employees, advisors, research collaborators, contractors or consultants independently develop, or use independently developed, intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises with respect to any proprietary right, enforcement of our rights can be costly and unpredictable, and a court may determine that the right belongs to a third party.

We may be subject to other patent-related litigation or proceedings that could be costly to defend and uncertain in their outcome.

In addition to infringement claims against us, we may in the future become a party to other patent litigation or proceedings before regulatory agencies, including interference or re-examination proceedings filed with the U.S. Patent and Trademark Office (USPTO) or opposition proceedings in other foreign patent offices regarding intellectual property rights with respect to our therapeutic candidates, as well as other disputes regarding intellectual property rights with our current and potential development and commercialization partners, or others with whom we have contractual or other business relationships. Post-issuance oppositions are not uncommon, and we and our current and potential development and commercialization partners will be required to defend these opposition procedures as a matter of course. Opposition procedures may be costly, and there is a risk that we may not prevail.

Risks Related to our Operations in Israel

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

We are incorporated in Israel. Most of our executive officers and directors reside outside of the U.S., and all of our assets and most of the assets of our executive officers and directors are located outside of the U.S. Therefore, a judgment obtained against us or such executive officers and our directors in the U.S., including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the U.S. and may not be enforced by an Israeli court. In addition, it may also be difficult for you to affect service of process on these persons in the U.S. or to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our non-U.S. officers and directors because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not United States law is applicable to the claim. If United States law is found to be applicable, the content of applicable United States law must be proven 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 that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment obtained in the United States against us or our non-U.S. officers and directors in Israel, it may be impossible to collect any damages awarded by either a U.S. or foreign court.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful shareholder claims against us and may reduce the amount of money available to us.

The Companies Law and our amended and restated articles of association permit us to indemnify our directors and officers for acts performed by them in their capacity as directors and officers. The Companies Law and our amended and restated articles of association provide that a company may not exempt or indemnify a director or an office holder nor enter into an insurance contract, which would provide coverage for any monetary liability incurred as a result of (a) a breach by the director or officer of his duty of loyalty, except for insurance and indemnification where the director or officer acted in good faith and had a reasonable basis to believe that the act would not prejudice the company; (b) a breach by the director or officer of his duty of care if the breach was done intentionally or recklessly, except if the breach was solely as a result of negligence; (c) any act or omission done with the intent to derive an illegal personal benefit; or (d) any fine, civil fine, monetary sanctions, or forfeit imposed on the officer or director.

We have issued letters of indemnification to our directors and officers, pursuant to which we have agreed to indemnify them in advance for any liability or expense imposed on or incurred by them in connection with acts they perform in their capacity as a director or officer, subject to applicable law. The amount of the advance indemnity will not exceed 25% of our then consolidated shareholders' equity, per our most recent consolidated annual financial statements.

Our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their duties as directors by shifting the burden of such losses and expenses to us. Although we have obtained directors' and officers' liability insurance, certain liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the coverage limitation amounts may be exceeded.

As a result of the class action motions and lawsuits or other claims which may be filed against our directors and officers, as well as the ISA Investigation, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to shareholders who may choose to bring a claim against our company. See the risk factor titled "*Legal proceedings or third-party claims of intellectual property infringement and other legal challenges may require us to spend substantial time and money and could prevent us from developing or commercializing our therapeutic candidates. An adverse result in these infringements and other legal challenges could have a material adverse effect on our business, results of operations and financial conditions*" under the risk factor section titled "Risks Related to Legal Proceedings and Intellectual Property".

These provisions and resultant costs may also discourage us from bringing a lawsuit against directors and officers for breaches of their duties and may similarly discourage the filing of derivative litigation by our shareholders against the directors and officers even though such actions, if successful, might otherwise benefit our shareholders.

We conduct our operations in Israel and therefore our results may be adversely affected by political, economic and military instability in Israel and its region as well as COVID-19 protocols in Israel.

We are incorporated under the laws of the State of Israel, our principal offices are located in central Israel and most of our officers, employees, consultants and directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. These conflicts have often involved missile strikes against civilian targets in various parts of Israel, and negatively affected business conditions in Israel. The tension between Israel and Iran or extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon, may escalate in the future and turn violent, which could affect the Israeli economy generally and us in particular.

Any hostilities involving Israel, or pandemics impacting Israel and its economy (such as the COVID-19 pandemic), related travel restrictions or quarantine, or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. Parties with whom we may do business have sometimes declined to travel to Israel during periods of heightened unrest or tension and have not been able to travel to Israel during the COVID-19 pandemic, forcing us to make alternative arrangements when necessary. The conflict situation in Israel, or COVID-19 (or other pandemic) related travel restrictions could cause situations where medical product certifying or auditing bodies could not be able to visit manufacturing facilities of our subcontractors in Israel in order to review our certifications or clearances, thus possibly leading to temporary suspensions or even cancellations of our product clearances or certifications. The conflict situation in Israel or the COVID-19 (or other pandemic) related travel restrictions, could also result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement 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. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts, terrorist activities or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business and trade activity with the State of Israel and with Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in the region continue or intensify. Such restrictions may seriously limit our ability to sell our products to customers in those countries.

If the current coronavirus outbreak continues and results in a prolonged period of travel, commercial and other similar restrictions to or from Israel could materially disrupt our business and operations, slow down the overall economy, and make it hard to adequately staff our operations.

Any of the factors set forth above may have an adverse impact on our operating results, financial condition or the expansion of our business.

Provisions of Israeli law and our amended and restated articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of the Company, or an acquisition of a significant portion of our shares, which could prevent a change of control, and negatively affect the market price of our ordinary shares.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for certain transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. These provisions of Israeli law may delay, prevent or make difficult an acquisition of us, which could prevent a change of control and therefore depress the price of our shares,

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders, especially for those shareholders whose country of residence does not have a tax treaty with Israel which exempts such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share exchange transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred.

In addition, our amended and restated articles of association also contain provisions that could delay or prevent changes in control or changes in our management. These provisions include matters in connection with the election and removal of directors, such as our staggered board of directors, the right of our board of directors to appoint additional directors to fill vacancies on the board of directors, the size of our board of directors, the terms of office of our directors and the special majority required to amend such provision in our amended and restated articles of association.

In addition, our amended and restated articles of association, we have 50,000,000 shares of authorized non-voting senior preferred shares, which can be issued by our board of directors, which can establish conversion, redemption, optional and other special rights, qualifications, limitations or restrictions, if any, of the non-voting senior preferred shares, without further action by our shareholders, unless shareholder approval is otherwise required by applicable law, the rules of any exchange or other market on which our securities may then be listed or traded, our articles of association then in effect, or any other applicable rules and regulations. Furthermore, in a merger between Israeli corporations, if the non-surviving entity has more than one class of shares, the merger may need to be approved by each class of shareholders, including any classes of otherwise non-voting shares, such as our authorized non-voting senior preferred shares.

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, or an acquisition of a significant portion of our shares, even if such an acquisition or merger would be beneficial to us or to our shareholders.

Because a certain portion of our expenses is incurred in currencies other than the U.S. dollar, our results of operations may be harmed by currency fluctuations and inflation.

Our reporting and functional currency is the U.S. dollar. Most of the royalty payments from potential development and commercialization partners are expected to be payable in U.S. dollars, and we expect our revenues from future licensing agreements to be denominated mainly in U.S. dollars. We pay a portion of our expenses in U.S. dollars; however, a portion of our expenses, related to salaries of our employees in Israel, our office lease and payment to part of the service providers in Israel, are paid in NIS and in other currencies such as euro to our suppliers in Europe. In addition, a portion of our financial assets is held from time to time in NIS. As a result, we are exposed to currency fluctuation risks. For example, if the NIS appreciates against the U.S. dollar, our NIS expenses as reported in U.S. dollars may be higher than anticipated. In addition, if the NIS depreciates against the U.S. dollar, the U.S. dollar value of our financial assets held in NIS will decline.

Your rights and responsibilities as a shareholder are governed by Israeli law. which may differ in some respects from the rights and responsibilities of shareholders of U.S. companies. Israeli law may impose obligations and responsibilities on a shareholder of an Israeli company that are not imposed upon shareholders of corporations in the U.S.

We are incorporated under Israeli law. The rights and responsibilities of the holders of our ordinary shares are governed by our amended and restated articles of association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders in typical 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 fulfilling its obligations toward 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 matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval under the Companies Law. In addition, a controlling shareholder of an Israeli company or a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or who has the power to appoint or prevent the appointment of a director or executive officer in the company or has other powers toward the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the implications of these provisions that govern shareholders' actions. These provisions may be interpreted to impose additional obligations and responsibilities on holders of our ordinary shares and/or ADSs that are not typically imposed on shareholders of U.S. corporations.

Our amended and restated articles of association designate courts located either within the State of Israel, or the Federal District Courts of the United States, as the exclusive forum for certain litigation that may be initiated by our shareholders, which could limit our shareholders' ability to bring a favorable or convenient judicial forum for disputes with us.

Our amended and restated articles of association provide that, unless we consent in writing to the selection of an alternative forum, the Tel Aviv District Court (Economic Division in the State of Israel (or, if the Tel Aviv District Court does not have jurisdiction, and no other Israeli court has jurisdiction, the federal district court for the District of New York) shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our shareholders, and (3) any action asserting a claim arising pursuant to any provision of the Companies Law or the Israeli Securities Law 5728-1968, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. In addition, the federal district courts of the United States for the District of New York shall be the exclusive forum for any complaint asserting a cause of action arising under the Securities Act of 1933. Any person or entity purchasing or otherwise acquiring any interest in our shares or ADSs shall be deemed to have notice of and consented to these provisions. This forum selection provision limits shareholders' choice in selecting a judicial forum for disputes with us that it finds favorable or convenient and may have the effect of discouraging lawsuits against us or our directors and officers.

Risks Primarily Related to Our ADSs and Ordinary Shares

The market price of our ordinary shares and ADSs is subject to fluctuation, which could result in substantial losses by investors.

The stock market in general, and the market price of our ordinary shares on the TASE and ADSs on NASDAQ, are subject to fluctuation, and changes in the price of our listed securities may be unrelated to our operating performance. The market prices of our ordinary shares on the TASE and ADSs on NASDAQ have fluctuated in the past, and we expect it will continue to do so. The market price of our ordinary shares and ADSs are and will be subject to a number of factors, including:

- announcements of technological innovations or new therapeutic candidates by us or by others;
- announcements by us of significant acquisitions, strategic partnerships, in-licensing, out-licensing, joint ventures or capital commitments;
- announcement by us of preclinical and clinical results;
- our need to raise additional capital;
- expiration or terminations of licenses, research contracts or other development or commercialization agreements;
- public concern as to the safety of drugs that we, our current or potential development and commercialization partners or others develop;
- the volatility of market prices for shares of biotechnology companies generally;
- success or failure of research and development projects;
- departure of key personnel;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares or ADSs are covered by analysts;
- changes in government regulations or patent decisions;
- developments by our current or potential development and commercialization partners; and
- general market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our ordinary shares and ADSs and result in substantial losses by investors.

Additionally, market prices for listed securities of biotechnology and pharmaceutical companies historically have been very volatile. The market for these listed securities has, from time to time, experienced significant price and volume fluctuations for reasons unrelated to the operating performance of any one company. In the past, following periods of market volatility, shareholders have often instituted securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and attention of management from our business, even if we are successful. See "*Legal proceedings or third-party claims of intellectual property infringement and other legal challenges may require us to spend substantial time and money and could prevent us from or delay us in developing or commercializing our therapeutic candidates. An adverse result in any infringement claim or other legal challenges could have a material adverse effect on our business, results of operations and financial condition*."

Future sales of our ordinary shares or ADSs or other warrants or convertible securities could reduce the market price of our ordinary shares and ADSs.

As of March 7, 2021, we had an aggregate of 175,105,742 issued and outstanding ordinary shares (including 1 dormant ordinary share held in treasury), no non-voting senior preferred shares, 4,595,005 non-listed warrants to purchase 4,595,005 ADSs (representing 45,950,050 ordinary shares) issued to investors, the underwriters and placement agents as part of a number of public and registered direct offerings by us, warrants to purchase up to an additional 403,779 ADSs (representing 4,037,805 ordinary shares) issued by us in January 2020 to former shareholders of FameWave in connection with our acquisition of FameWave, and non-tradable options and restricted stock units to purchase 10,384,380 ordinary shares pursuant to our equity based incentive compensation plans and arrangements.

Any future sales by us or our shareholders of a substantial number of our ordinary shares or ADSs or other warrants or securities convertible into ordinary shares or ADSs, or the perception that such sales may occur in the future, including sales of ordinary shares or ADSs issuable upon the exercise of options or the conversion of convertible securities, may cause the market price of our ordinary shares or ADSs or other listed securities to decline.

NASDAQ has a listing requirement of a minimum closing bid price of $1.00 per share. If our ADSs cannot maintain the required minimum closing bid price and we fail to correct the listing requirement deficiency within the provided cure period, our ADSs may be involuntarily delisted from NASDAQ.

Our ADSs are listed on NASDAQ, and the quantitative listing standards of NASDAQ require, among other things, that listed companies maintain a minimum closing bid price of $1.00 per ADS. On July 8, 2019, we received a letter from the Listing Qualifications Department of NASDAQ indicating that, based upon the closing bid price of our ADSs for the last 30 consecutive business days, we did not meet the minimum bid price of $1.00 per share required for continued listing on NASDAQ pursuant to NASDAQ Listing Rule 5550(a)(2). We were not able to regain compliance with this requirement within the 180-day period ending on January 6, 2020, but we were granted an extension until September 18, 2020, to regain compliance with this requirement. On August 21, 2020, we changed the ratio of our ADSs to ordinary shares from one (1) ADS representing one (1) ordinary share to a new ratio of one (1) ADS representing ten (10) ordinary shares, the primary purpose of which was to enable us to regain compliance with the $1.00 minimum bid price requirement. On September 4, 2020, we received a notification letter from Listing Qualifications Department of NASDAQ stating that it had determined that for ten consecutive business days (from August 21, 2020 through September 3, 2020), the closing bid price of our ADS had been at $1.00 per ADS or greater, and accordingly we had regained compliance with the minimum bid price for continued listing on NASDAQ.

Although we have regained compliance with the minimum bid price requirement, if we are unable to satisfy the minimum bid price requirement in the future and should a delisting occur, an investor would likely find it significantly more difficult to dispose of, or to obtain accurate quotations as to the value of our ADSs, and our ability to raise future capital through the sale of our ADSs could be severely limited. Delisting would also impact some of our disclosure obligations under Israeli law. Following a delisting, we would remain a publicly traded company on TASE and revert to being subject to full Israeli securities laws and disclosure requirements. Accordingly, we would need to comply with U.S. and Israeli disclosure requirements, which would likely lead to additional legal and financial compliance costs and require significant management time.

In the event that our ADSs are delisted from NASDAQ, U.S. broker-dealers may be discouraged from effecting transactions in shares of our ADSs because they may be considered penny stocks and thus be subject to the penny stock rules.

The SEC has adopted a number of rules to regulate "penny stock" that restrict transactions involving stock which is deemed to be penny stock. Such rules include Rules 3a51-1, 15g-1, 15g-2, 15g-3, 15g-4, 15g-5, 15g-6, 15g-7, and 15g-9 under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"). These rules may have the effect of reducing the liquidity of penny stocks. "Penny stocks" generally are equity securities with a price of less than $5.00 per share (other than securities registered on certain national securities exchanges or quoted on NASDAQ if current price and volume information with respect to transactions in such securities is provided by the exchange or system). Following a delisting from NASDAQ our ADSs may constitute "penny stock" within the meaning of these rules. The additional sales practice and disclosure requirements imposed upon U.S. broker-dealers may discourage such broker-dealers from effecting transactions our ADSs, which could severely limit the market liquidity of such ADSs and impede their sale in the secondary market.

A U.S. broker-dealer selling penny stock to anyone other than an established customer or "accredited investor" (generally, an individual with net worth in excess of $1,000,000 or an annual income exceeding $200,000, or $300,000 together with his or her spouse) must make a special suitability determination for the purchaser and must receive the purchaser's written consent to the transaction prior to sale, unless the broker-dealer or the transaction is otherwise exempt. In addition, the "penny stock" regulations require the U.S. broker-dealer to deliver, prior to any transaction involving a "penny stock", a disclosure schedule prepared in accordance with SEC standards relating to the "penny stock" market, unless the broker-dealer or the transaction is otherwise exempt. A U.S. broker-dealer is also required to disclose commissions payable to the U.S. broker-dealer and the registered representative and current quotations for the securities. Finally, a U.S. broker-dealer is required to submit monthly statements disclosing recent price information with respect to the "penny stock" held in a customer's account and information with respect to the limited market in "penny stocks".

Securities holders should be aware that, according to the SEC, the market for "penny stocks" has suffered in recent years from patterns of fraud and abuse. Such patterns include (i) control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer; (ii) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (iii) "boiler room" practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (iv) excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and (v) the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, resulting in investor losses.

We incur increased costs and risks as a result of operating as a public company in the U.S. and Israel, and our management is and will continue to be required to devote substantial time to compliance initiatives.

Our ADSs have been traded on The NASDAQ Capital Market since November 20, 2015, and prior to that our ordinary shares traded on the TASE, where they continue to trade. As a public company whose securities are listed in the United States and Israel, we incur accounting, legal and other expenses, including costs associated with our reporting requirements under the Exchange Act and the Israeli Securities Law. We also incur costs associated with corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, as well as rules implemented by the SEC and NASDAQ, and provisions of Israeli corporate and securities laws applicable to public companies. Certain aspects of Israeli securities laws are different than U.S. securities law, and our dual listing on TASE exposes us and our management to differing regulatory regimes which may involve increased regulatory risk.

We ceased to qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act, as of December 31, 2020, which was the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering on NASDAQ on November 25, 2015. As a result, we can no longer take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes Oxley Act (and the rules and regulations of the SEC thereunder). We expect to incur additional expenses and devote increased management effort toward ensuring compliance with such additional reporting requirements.

Pursuant to Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the SEC and the Public Company Accounting Oversight Board, our management is required to report on the effectiveness of our internal control over financial reporting. In addition, since we no longer qualify as an "emerging growth company" under the JOBS Act, our independent registered public accounting firm is also required to attest to the effectiveness of our internal control over financial reporting under Section 404.

The process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls, requires the investment of substantial time and resources, including by our chief executive officer, chief financial officer and other members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete.

We cannot predict the outcome of evaluations we will conduct in the future, and whether we will need to implement additional remedial actions in order to implement effective controls over financial reporting. The determination and any remedial actions required could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. Irrespective of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our independent auditors and cause the market price of our ordinary shares and ADSs to decline.

Changes in the laws and regulations affecting public companies may result in increased costs to us as we respond to their requirements. These laws and regulations could make it more difficult or costlier for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We cannot predict or estimate the amount or timing of additional costs we may incur in order to comply with such requirements.

We may be classified as a Passive Foreign Investment Company, or PFIC, for U.S. federal income tax purposes in 2021 and may continue to be, or become, a PFIC in future years, which may have negative tax consequences for U.S. investors.

We will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of our gross income is "passive income" or (ii) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Based on our estimated gross income, the average value of our gross assets, and the nature of our business, we believe it is likely that we were a PFIC in 2020 and we may also be classified as a PFIC in future years. If we are treated as a PFIC for any taxable year during which a U.S. investor held our ADSs, certain adverse U.S. federal income tax consequences could apply to the U.S. investor.

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of applicable NASDAQ requirements, which may result in less protection than is accorded to investors under rules applicable to U.S domestic issuers.

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the NASDAQ Listing Rules for U.S domestic issuers. We follow home country practice in Israel with regard to (among other things) director nomination procedures, quorum requirement at shareholder meetings and approval of related party transactions and executive compensation. In addition, we follow our home country law, instead of the NASDAQ Listing Rules, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity-based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the Company and certain acquisitions of the stock or assets of another company. In the future we may elect to follow additional home country corporate governance practices instead of those otherwise required under the NASDAQ Listing Rules for U.S domestic issuers. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on NASDAQ may provide less protection than is accorded to investors under the NASDAQ Listing Rules applicable to domestic issuers. See "Item 16G. Corporate Governance."

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, as a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as domestic companies whose securities are registered under the Exchange Act. We intend to file with the SEC, within 120 days after the end of each fiscal year ending December 31, an annual report on Form 20-F containing financial statements which will be examined and reported on, with an opinion expressed, by an independent registered public accounting firm. In accordance with NASDAQ Listing Rules, as a foreign private issuer we are required to submit on a Form 6-K an interim balance sheet and income statement as of the end of the second quarter of each fiscal year. Foreign private issuers are also exempt from Regulation FD, which is intended to prevent issuers from making selective disclosures of material information. As a result of all of the above, you may not have the same protections afforded to shareholders of a company that is not a foreign private issuer.

We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

As discussed above, we are a foreign private issuer, and therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter, and, accordingly, the next determination will be made with respect to us on June 30, 2021. In the future, we would lose our foreign private issuer status if (1) more than 50% of our outstanding voting securities are owned by U.S. residents and (2) a majority of our directors or executive officers are U.S. citizens or residents, or we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. If we lose our foreign private issuer status, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms, which are more detailed and extensive than the forms available to a foreign private issuer. We will also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements under the NASDAQ Listing Rules. As a U.S. listed public company that is not a foreign private issuer, we will incur significant additional legal, accounting and other expenses that we do not incur as a foreign private issuer.

Our ADS holders may not be able to fully exercise their voting rights to the same extent as our ordinary shareholders. The depositary for our ADSs will give us a discretionary proxy to vote our ordinary shares underlying ADSs if a holder of our ADSs does not provide voting instructions, except in limited circumstances, which could adversely affect their interests.

Our ADS holders may instruct the depositary how to vote the number of deposited ordinary shares their ADSs represent. Except by instructing the depositary, you will not be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested, and you cannot vote in person at meetings as a holder of ADSs.

Under the deposit agreement for the ADSs, the depositary will give us a discretionary proxy to vote our ordinary shares underlying ADSs at shareholders' meetings if a holder of our ADSs does not provide voting instructions, unless we notify the depositary that:

- we do not wish to receive a discretionary proxy;
- there is substantial shareholder opposition to the particular question; or
- the particular question would have an adverse impact on our shareholders.

The effect of this discretionary proxy is that a holder of our ADSs cannot prevent our ordinary shares underlying such ADSs from being voted, absent the situations described above, and it may make it more difficult for shareholders to influence the management of our company. Holders of our ordinary shares listed for trading on the TASE are not subject to this discretionary proxy.

We currently do not anticipate paying cash dividends, and accordingly, shareholders must rely on the appreciation in our ordinary shares and ADSs for any return on their investment.

We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. The ability of an Israeli company to pay dividends or repurchase its shares is governed by Israeli law, which provides that unless otherwise approved by a court, distributions, including cash dividends and share repurchases, may be made only out of retained earnings as determined for statutory purposes, and only if there is no reasonable concern that the dividend distribution will prevent us from meeting our existing and foreseeable obligations, as they become due. Subject to the foregoing, payment of future dividends, if any, will be at the discretion of our board of directors and will depend on various factors, such as our financial condition, operating results, current and anticipated cash needs and other business and economic factors that our board of directors may deem relevant. Since we do not have earnings, we currently do not have any ability to pay dividends or repurchase our shares, absent court approval. Therefore, the success of an investment in our ordinary shares and ADSs will depend upon any future appreciation in their value. There is no guarantee that our ordinary shares and ADSs will appreciate in value or even maintain the price at which our holders have purchased their share and ADSs.

Investors in our ADSs may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, investors in our ADSs may not receive any value for them, if it is illegal or impractical to make them available to investors in our ADSs.

The depositary for the ADSs has agreed to pay investors in our ADSs the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. Investors in our ADSs will receive these distributions in proportion to the number of ordinary shares their ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act of 1933, as amended or the Securities Act, but that are not properly registered or distributed under an applicable exemption from registration. In addition, conversion into U.S. dollars from foreign currency that was part of a dividend which was distributed in foreign currency made in respect of deposited ordinary shares may require the approval or license of, or a filing with, any government or agency thereof, which may be unobtainable. In these cases, the depositary may determine not to distribute such property and hold it as "deposited securities" or may seek to affect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the depositary deems an equitable and practicable substitute. We have no obligation to register under U.S. securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. In addition, the depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that investors in our ADSs may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, investors in our ADSs may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to investors in our ADSs. These restrictions may cause a material decline in the value of the ADSs.

Holders of ADSs must act through the depositary to exercise rights of shareholders of our company.

Holders of our ADSs do not have the same rights as our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement for the ADSs. Under Israeli law, the minimum notice period required to convene a shareholders' meeting is no less than 35 or 21 calendar days, depending on the proposals on the agenda for the shareholders' meeting. When a shareholder meeting is convened, holders of our ADSs may not receive sufficient notice of the meeting to permit them to withdraw their ordinary shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send notice to holders of our ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of our ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote the ordinary shares underlying their ADSs. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of our ADSs may not be able to exercise their right to vote and they may lack recourse if the ordinary shares underlying their ADSs are not voted as they requested. In addition, ADS holders will not be able to call a shareholders' meeting unless they first withdraw their ordinary shares from the ADS program and receive delivery of the underlying ordinary shares held in the Israeli market in order to allow them to submit to us a request to call a meeting with respect to any specific matter, in accordance with the applicable provisions of the Companies Law and our amended and restated articles of association.

Our ordinary shares and our ADSs are traded on different markets and this may result in price variations.

Our ordinary shares trade on the TASE, and our ADSs trade on NASDAQ. Trading on these markets take place in different currencies (U.S. dollars on NASDAQ and NIS on the TASE), and at different times (resulting from different time zones, different trading days and different public holidays in the U.S. and Israel). The trading prices of our securities on these two markets may differ due to these and other factors. Any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

Our ADSs have a limited trading history in the U.S., and present level of market activity may not be sustained, which may limit the ability of our investors to sell our ADSs in the U.S.

Although our ADSs have been traded on NASDAQ since November 20, 2015, the present level of market activity for our ADSs may not be sustained. If an active market for our ADSs is not sustained, it may be difficult for an investor to sell its ADSs.

We can issue non-voting senior preferred shares without shareholder approval, which could adversely affect the rights of holders of ordinary shares.

Our amended and restated articles of association permit us to establish the rights, privileges, preferences and restrictions of future series of our non-voting senior preferred shares, which contain superior liquidation and dividend rights, and may contain other rights, including conversion, redemption, optional and other special rights, qualifications, limitations or restrictions, equivalent or superior to our ordinary shares and to issue such non-voting senior preferred shares without further approval from our shareholders. The rights of holders of our ordinary shares may suffer as a result of the rights granted to holders of non-voting senior preferred shares that we may issue in the future. In addition, we could issue non-voting senior preferred shares containing rights that prevent a change in control or merger, thereby depriving holders of our ordinary shares of an opportunity to sell their shares at a price in excess of the prevailing market price.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our ADSs, the price of our ADSs could decline.

The trading market for our ADSs will rely in part on the research and reports that equity research analysts publish about us and our business. The price of our ADSs could decline if such research or reports are not published or if one or more securities analysts downgrade our ADSs or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

We have broad discretion as to the use of the net proceeds from our previous offerings and may not use them effectively.

We currently intend to use the net proceeds from our previous offerings to expand our clinical development program, expand our clinical development pipeline for additional drug products, including by way of possible acquisitions, and for general corporate purposes, including working capital requirements. However, our management will have broad discretion in the application of the net proceeds from our previous offerings. Our shareholders may not agree with the manner in which our management chooses to allocate the net proceeds from our previous offerings. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operations. Pending their use, we may invest the net proceeds from our previous offerings in a manner that does not produce income. The decisions made by our management may not result in positive returns on any investment by shareholders and shareholders will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

General Risk Factors

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. An economic downturn could result in a variety of risks to our business, including weakened demand for our therapeutic candidates and our inability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our partners and suppliers, possibly resulting in supply disruption, or cause future customers to delay making payments for our products. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

We were incorporated under the laws of the State of Israel (under a previous name) on August 12, 1968. Our ordinary shares were originally listed for trading on the TASE in 1978 and our ADSs have been traded on NASDAQ since November 2015. Our ordinary shares are currently traded on the TASE under the symbol "PPBT", and our ADSs are currently traded on NASDAQ under the symbol "PPBT". The Company is headquartered in Rehovot, Israel and our telephone number is +972-3-933-3121. Our website address is www.purple-biotech.com, and our telephone number is +972-3-933-3121. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report and is not incorporated by reference herein. We have included our website address in this Annual Report solely for informational purposes. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers, such as us, that file electronically with the SEC at www.sec.gov.

In October 2012, the District Court in Lod, Israel approved the creditors arrangement in accordance with Section 350 of the Companies Law in order to effectuate the sale by our company (then known as Mainrom Line Logistics Ltd.) of all its activities, assets, rights, obligations and liabilities to a private company held by its then controlling shareholders, and all rights of our creditors against us were extinguished. From the completion of these transactions until the completion of the acquisition of Kitov Pharmaceuticals described below, Purple Biotech (then known as Kitov Pharma) did not conduct any business activities and was a public shell company listed on the TASE with no assets, debt and/or liabilities.

On July 11, 2013, we acquired Kitov Pharmaceuticals, which, prior to the completion of its merger with and into our company in December 2017, together with our company, was engaged in the research and development of Consensi. As part of the acquisition, Mainrom Line Logistics Ltd. changed its name to Kitov Pharmaceuticals Holdings Ltd., which name was subsequently changed in January 2018 to Kitov Pharma Ltd.

On January 13, 2017, we announced that we had acquired a majority equity stake in TyrNovo, a privately held developer of novel small molecules in the oncology therapeutic field.

On April 25, 2017, the boards of directors of each of Kitov Pharma and Kitov Pharmaceuticals approved a merger between the two entities, with Kitov Pharma remaining as the surviving entity. The merger was completed in December 2017. Kitov Pharmaceuticals was dissolved upon the merger, and Kitov Pharma remained as the surviving entity.

In January 2020, we completed the acquisition of FameWave, a privately held developer of CM24 in the oncology therapeutic field.

On December 7, 2020, we changed our name to Purple Biotech Ltd.

We had no material capital expenditures for the years ended December 31, 2020, 2019 and 2018.

B. Business Overview

We are a clinical-stage company developing first-in-class, effective, and durable therapies by overcoming tumor immune evasion and drug resistance.

We currently have two operating segments:

(i) Oncology, which includes CM24, a humanized monoclonal antibody that blocks Carcinoembryonic Antigen Related Cell Adhesion Molecule 1 ("CEACAM1"), an immune checkpoint protein that supports tumor immune evasion and survival through multiple pathways, and NT219, a small molecule that simultaneously targets Insulin Receptor Substrate 1 and 2 ("IRS1/2") and Signal Transducer and Activator of Transcription ("STAT3"), two signal transduction pathways involved in the development of cancer drug resistance mechanisms. Within the Oncology segment:

- We are advancing CM24 as a combination therapy with anti-PD-1 checkpoint inhibitors in selected cancer indications in a phase 1 study followed by a phase 2 for the treatment of non-small cell lung cancer and pancreatic cancer. We have entered into a clinical collaboration agreement, as amended, with Bristol Myers Squibb for the planned phase 1/2 clinical trials to evaluate the combination of CM24 with the PD-1 inhibitor nivolumab (Opdivo) in patients with non-small cell lung cancer and in combination with nivolumab in addition to nab-paclitaxel (ABRAXANE) in patients with pancreatic cancer; and

- In the second half of 2020 we commenced a phase 1/2 study of NT219 as a single agent in patients with solid tumors, followed by a dose escalation phase of NT219 in combination with cetuximab for the treatment of recurrent and/or metastatic solid tumors and squamous cell carcinoma of the head and neck cancer or colorectal adenocarcinoma, and an expansion phase of NT219 at its recommended phase 2 level in combination with cetuximab in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck.

(ii) Pain and Hypertension, which includes Consensi, a combination drug approved by the FDA for the simultaneous treatment of two clinical conditions, pain caused by osteoarthritis and hypertension (high blood pressure). In May 2020, we launched the U.S. commercial sales of Consensi, which is being sold in the U.S. by Burke Therapeutics, the marketing partner of our U.S. distributor, Coeptis.

In addition, we may consider the acquisition of oncology therapeutic candidates at various stages of development. We currently have no binding agreements or commitments to complete any transaction for the possible acquisition of new therapeutic candidates or approved drug products.

Background on our therapeutic candidates and products

In January 2020 we acquired FameWave, a privately held biopharmaceutical company, whose main asset is CM24, a clinical stage humanized monoclonal antibody directed against CEACAM1, an immune checkpoint protein belonging to the Human CEA (Carcino-Embryonic Antigen) protein family. Evidence has shown that CEACAM1 is expressed on tumor lymphocytes and is up-regulated in several cancer types. Preclinical studies have shown evidence that CM24 enhances the cytotoxic activity of tumor-infiltrating lymphocytes (TILs) against various CEACAM1-positive tumor cell lines. CM24 is being developed for multiple oncological indications according to the expression pattern of its target protein. Preclinical studies provide strong justification for CM24's mechanism of action in activating the immune system through multiple pathways. Additional preclinical studies showed that a combination of CM24 with PD-1 and PDL-1 antibodies resulted in a synergistic anti-cancer effect. In a Phase 1 dose ranging study of CM24 as a single agent, conducted by Merck Sharp and Dohme Corp., or MSD, a stable disease rate of approximately 33% among the evaluable patients was noted. A decision was made by MSD to discontinue development, although, based on our knowledge, such decision was not due to any known safety risks. We are advancing CM24 as a combination therapy with anti-PD-1 checkpoint inhibitors in selected cancer indications in a phase 1 study followed by a phase 2 for the treatment of non-small cell lung cancer and pancreatic cancer. We have entered into a clinical collaboration agreement, as amended, with Bristol Myers Squibb for the planned phase 1/2 clinical trials to evaluate the combination of CM24 with the PD-1 inhibitor nivolumab (Opdivo) in patients with non-small cell lung cancer and in combination with nivolumab in addition to nab-paclitaxel (ABRAXANE) in patients with pancreatic cancer. For more information regarding CM24, see, "Item 4. Business Overview - Our Therapeutic Candidates – CM24".

During 2017, we acquired a majority of the shares in TyrNovo, a privately held developer of novel small molecules in the oncology therapeutic field. TyrNovo has developed NT219, a novel small molecule that presents what we believe to be a new concept in cancer therapy by targeting two key oncology-related proteins, IRS1/2, as well as STAT3. Our NT219 therapeutic candidate's anti-cancer effect is achieved by overcoming tumors' cancer drug resistance and would be developed both as a standalone drug, as well as in combination with other cancer drugs or treatments. NT219 has been tested in a number of Patient-Derived Xenograft (PDX) models where human cancer biopsies were taken and transplanted into mice and then used to test various cancer drugs. NT219 has been pre-clinically tested alone and in combination with various classes of cancer drugs such as with chemotherapies, targeted therapies and immuno-oncology therapies. In the second half of 2020 we commenced a phase 1/2 study of NT219 as a single agent in patients with solid tumors, followed by a dose escalation phase of NT219 in combination with cetuximab for the treatment of recurrent and/or metastatic solid tumors and squamous cell carcinoma of the head and neck cancer or colorectal adenocarcinoma, and an expansion phase of NT219 at its recommended phase 2 level in combination with cetuximab in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck. For more information regarding NT219, see, "Item 4. Business Overview - Our Therapeutic Candidates – NT219".

Consensi is composed of the generic substances celecoxib and amlodipine besylate. Celecoxib, the active ingredient in the branded drug Celebrex, is a non-steroidal anti-inflammatory drug (NSAID) used to relieve pain caused by osteoarthritis. Amlodipine besylate is a calcium channel blocker used to reduce blood pressure. This combination is designed to simultaneously relieve pain caused by osteoarthritis and to treat hypertension. In May 2020, we launched the U.S. commercial sales of Consensi, which is being sold in the U.S. by Burke Therapeutics**.**

Our competitive strengths

The pharmaceutical market is characterized by large international pharmaceutical companies that develop a wide range of products, both generic and innovative, which operate alongside smaller companies, such as ours, that develop a specific drug or a combination of drugs. Therefore, many small companies enter into agreements with such global companies during the drug development stage in order to continue the development or marketing of the drug, taking advantage of the financial, marketing and/or other resources available to such global companies. At the same time, the global companies tend to enter into agreements with smaller companies in order to save development time and resources. The global drug sector is a highly developed market with a turnover of hundreds of billions of U.S. dollars and intense competition. If we are to develop other therapeutic candidates and one or more of those therapeutic candidates are approved by the FDA to be commercialized as drugs, most of those drugs are expected to have competing drugs or other therapies, developed at the same time by other companies and organizations. We are therefore exposed to competition in our field of operation. Although we believe that our FDA-approved drug Consensi and our oncology therapeutic candidates have advantages which our competitors' products lack, there is a constant risk in the drug development field that a competing party will complete the development stages before we are able to develop our therapeutic candidates intended for the same disease. Moreover, a constant threat in our market is presented by new drugs that have already completed all the development stages and have already entered the market and are competing with the treatments and drugs previously available on the market.

We believe there are several advantages to the therapeutic candidate we are developing and to our products as set forth below.

Oncology Segment - CM24:

CEACAM1 is unique among the CEACAM family members in that it is widely distributed among various species and it has the largest number of splice variants compared to other members of the family. Moreover, CEACAM1 also has the widest tissue distribution of all characterized family members. as the widest tissue distribution of all characterized family members (source: Current Opinion in Cell Biology Volume 18, Issue 5, October 2006, Pages 565-571). Accordingly, CM24 may have a competitive advantage over other CEACAM-targeting agents in that its inhibitory effect may be more general and target several splice variants and more tissues.

Additional potential advantages of CM24 over other CEACAM-targeting technologies may include:

- As CM24 blocks the homo- as well as the hetero-dimerization, i.e. blocks both CEACAM1-CEACAM1 as well as CEACAM1-CEACAM5 interaction - it has the potential to be more effective in controlling the contact inhibition of cancerous cells with cells of the immune system. CM24 acts as an immune adhesion inhibitor molecule – a mechanism that is central to the immune evasion mechanism of neoplastic cells.

- In addition to its contribution to tumor suppression CEACAM1 also has a modulatory role in multiple cell types such as epithelial cells, endothelial cells, T-cells and hepatocytes.

- CEACAM1 is a ligand for T-cell Immunoglobulin and Mucin domain-3 (TIM-3) – another immune checkpoint inhibitor. By activating TIM-3 with CM24, a synergistic effect may be expected. The relationship between CEACAM1 and TIM-3 has recently been described as a mechanism that may overcome immune fatigue and T-cell exhaustion (Nature. 2015 Jan 15; 517(7534): 386–390; Acharya N, et al. J Immunotherapy 8:e911-22, 2020).

- CEACAM1 has been associated with trophism for cancer cells and the metastatic phenotype manifest through neutrophil extracellular traps (Rayes RF, et al. J Immunology. 2020).

Finally, CM24 has been in a Phase 1 clinical trial, where 27 patients were treated with the monoclonal antibody without needing to discontinue the dosing of CM24 due to adverse events, no drug related mortalities and no dose limiting toxicities up to 10mg/kg, the highest dose tested.

Oncology Segment - NT219:

NT219 is a small molecule, and small molecules typically are less expensive to develop and have less complex CMC as compared to proteins or antibodies. In addition, in pre-clinical development NT219 has demonstrated several advantageous effects, such as:

- single agent activity in PDX models and xenografts;
- overcoming drug resistance acquired by various cancer types; and
- efficacy in combination with a number of approved cancer therapies belonging to various anti-cancer drug classes such as chemotherapy, targeted therapy and immune-oncology therapies.

Pain and Hypertension Segment - Consensi:

Consensi is an FDA approved fixed-dose combination drug treatment intended for the treatment of osteoarthritis pain and for hypertension. In Phase 3 and Phase 3/4 clinical trials, Consensi demonstrated non-inferiority in lowering blood pressure than amlodipine alone (one of Consensi's ingredients). In addition, we believe there are several advantages of using Consensi:

- using one drug that also includes an active ingredient that treats hypertension either as an existing condition or as a side effect of using other drugs, ensures that the patient receives the suitable treatment for their disease and for its side effect;
- reassuring physicians who are concerned that their patients who are treated for osteoarthritis will also be treated for hypertension, which is a known side effect of NSAID treatments for pain caused by osteoarthritis. This is a particular concern, as hypertension is usually not accompanied by tangible symptoms, and therefore patients may not be aware of their condition or the need to treat it;
- purchasing one drug as opposed to purchasing two separate drugs may lead to financial savings for patients in the U.S. by requiring payment of just one co-payment and prescription fee as opposed to a double co-payment and prescription fee. In addition, the use of one combination drug reduces the patient's discretion with respect to whether to purchase and use only one of the drugs and provides a comprehensive dual medical treatment in one combined drug; and
- using calcium channel blockers in our therapeutic candidates as an antihypertensive. Calcium channel blockers are not included in the FDA Safety Information Release for NSAIDs co-administered with angiotensin converting enzyme inhibitors, or ACE inhibitors, or with angiotensin II receptor antagonists, diuretics and beta blockers.

Our strategy

Our goal is to become a significant player in the development and commercialization of innovative drugs that treat unmet medical needs and can capitalize on significant market opportunities, focusing on oncology therapeutics.

Key elements of our strategy are to:

- focus on oncology therapeutic assets for treatment of unmet medical need and having a significant market opportunity;
- leverage our expertise in the clinical and regulatory processes in the United States, together with our research and development capabilities and network of professional advisors, to efficiently develop drug candidates in clinical stages of development and achieve marketing authorization;
- expand our line of therapeutic candidates through the acquisition or in-licensing of technologies, products and drugs in the oncology space intended to meet clinical needs;

- cooperate with third parties to both develop and commercialize therapeutic candidates in order to share costs and leverage the expertise of others; and

- secure sufficient funds for the performance of acquisitions and development programs.

Our oncology therapeutic candidates CM24 and NT219 and our current approved product, Consensi, are further described below.

Oncology Segment – CM24

Background

CM24 is a humanized monoclonal antibody directed against CEACAM1, an immune checkpoint protein belonging to the Human CEA (Carcino-Embryonic Antigen) protein family. Evidence has shown that CEACAM1 is expressed on tumor infiltrating lymphocytes and is up-regulated in several cancer types. Moreover, CEACAM1 is associated with mechanisms of trophism and metastases in cancer, manifest through mechanisms such as neutrophil extracellular traps.

The technology originated from the laboratory of Professor Gal Markel from Sheba Medical Center and initially developed by cCAM, which was acquired by MSD in 2015.

MSD conducted a phase 1 clinical trial, including patients with metastatic melanoma, non-small cell lung cancer, bladder, gastric, colorectal and ovarian cancer patients. In this initial Phase 1 dose ranging study of CM24 as single agent, a stable disease rate of approximately 33% among the evaluable patients was noted as best overall response among the evaluable patients, and the decision was made to discontinue development, although, based on our knowledge, such decision was not due to any known safety risks. MSD therefore returned the rights of CM24 to former cCAM shareholders and founders of FameWave. Review of the Phase 1 study results by external scientific advisors retained by us suggested that while CM24 was generally safe, higher doses of the antibody along with a modified dosing regimen in a defined patient population would be warranted. We plan to explore higher doses of CM24, up to 20mg/kg, and to test the antibody in combination with an anti-PD-1 antibody (nivolumab).

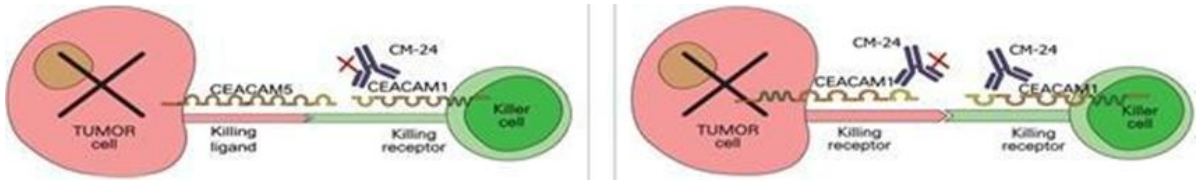
The Therapeutic Candidate

CM24 is a humanized immunoglobulin G4 (IgG4) isotype immune-modulating monoclonal antibody that binds to CEACAM1, a protein used by cancer cells to suppress the immune system.

CEACAM1 belongs to the CEA superfamily. CEACAM1 interacts with itself (i.e., hemophilic interaction) and with CEACAM5 (heterophilic interaction), as well as with various bacterial proteins. Different functions have been attributed to the CEACAM1 protein: anti-proliferative properties in carcinomas of the colon and prostate, or facilitation of proliferation in melanoma; central involvement in angiogenesis, insulin clearance and in immune-modulation. CEACAM1 is expressed by many types of tumors and is associated with poor prognosis in cutaneous melanoma, uveal melanoma, hepatocellular carcinoma, colorectal cancer and lung cancer. In addition, increased CEACAM1 expression on peripheral blood lymphocytes and elevated serum CEACAM1 were observed in patients with melanoma, osteosarcoma and pancreatic carcinoma. These collective observations provide a strong justification for the development of a therapeutic approach that targets the immuno-suppressive function of CEACAM1.

Earlier preclinical studies revealed CM24 reversed CEACAM1-mediated immune evasion by abrogating CEACAM1-CEACAM1 interactions, restoring ZAP70 phosphorylation and TCR-driven effector functions, while maintaining antigen-restricted recognition. This abrogates the immunosuppressive function of CEACAM1, promoting cell killing by T cells and NK cells.

CM24 is a blocking monoclonal antibody that prevents CEACAM1-CEACAM1 and CEACAM1-CEACAM5 interactions, thus enhancing the cytotoxic activity of lymphocytes.



Preclinical and Mechanism of Action and Target Validation

The preclinical studies have shown evidence that CM24 enhances the cytotoxic activity of tumor-infiltrating lymphocytes (TILs) against various CEACAM1-positive tumor cell lines. Additional preclinical studies provide strong justification for CM24's mechanism of action in activating the immune system through multiple pathways as validated by world renowned researchers at Harvard Medical School and MIT, in an article published in Nature* as well as by Prof. Gal Markel from the Tel HaShomer Medical Center**. Additional preclinical studies showed that a combination of CM24 with a PD-1 antibody resulted in a synergistic anti-cancer effect.

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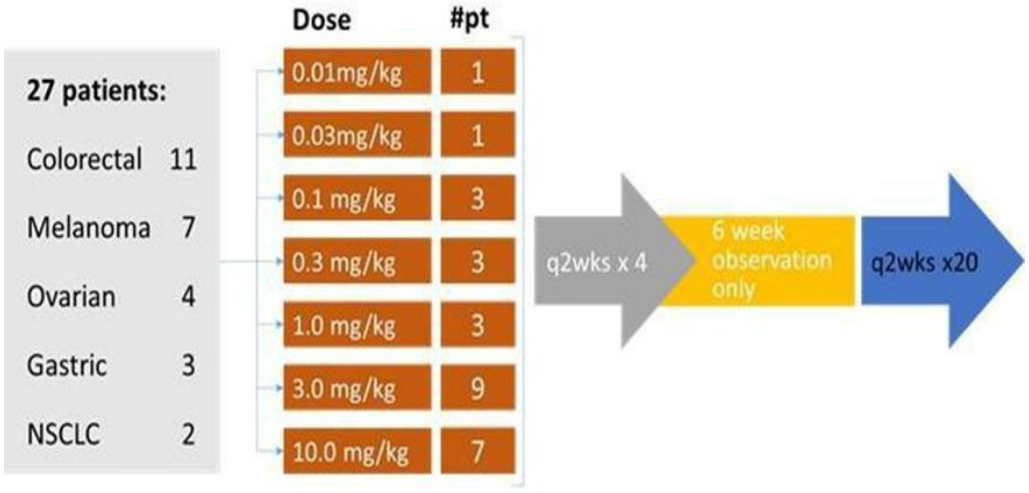
* Huang Y-H, et al., (2015) Nature, 517(7534): 386–390. doi:10.1038/nature13848

** Markel G., et al., (2006) J Immunol., 177:6062-6071; doi: 10.4049/jimmunol.177.9.6062

Phase 1 Clinical Trial

MSD conducted an interventional, Phase 1, first in human, non-randomized, single group assignment, open-label, multi-centered and multiple escalating doses study to assess the safety, efficacy, pharmacokinetics and tolerability of the CM24 antibody in the treatment of subjects with selected advanced or recurrent malignancies including melanoma, non-small cell lung adenocarcinoma (NSCLC) and bladder, gastric, colorectal or ovarian cancer.

The main objectives of the MSD clinical study were to assess the safety and tolerability of CM24 and to determine the recommended dose for Phase 2 trials, characterization of the pharmacokinetic profile and immunogenicity of CM24, and to evaluate the preliminary efficacy of the drug. The trial was conducted at four sites in the U.S. and Israel and was designed based on a dose escalation stage and an expansion stage. MSD terminated the trial following administration of CM24 to 27 patients and prior to reaching the expansion stage.



Main conclusions by us from the Phase 1 clinical trials results:

- CM24 was found to be generally safe and well tolerated. There were no DLTs up to 10mg/kg and no drug related morbidity
- Target saturation was not reached up to 10mg/kg. PK modeling suggests that slower clearance with increasing dose and higher half-life with increasing dose, PK variability across patients, and full receptor occupancy may likely require doses >10mg/kg administered every 2 weeks
- Treatment related adverse events noted in 17 subjects: 82% Grade 1, 16% Grade 2 and 2.7% Grade 3. Most frequent were increased LFTs and anorexia. The two Grade 3 events were headache and abdominal pain; there were 2 deaths that occurred within 30 days from the last administration of CM24 due to disease progression.
- A stable disease rate of approximately 33% among the evaluable patients was achieved, mostly in the two highest dose groups, where half of the evaluable patients achieved stable disease.

Our Clinical Development Plans for CM24

We believe that CM24 is a promising agent, which has a potential to be efficacious as a standalone and in combination with other anti-cancer agents, including anti PD-1 agents and other checkpoint inhibitors for patients with cancer. The Phase 1 study noted above showed that CM24 was generally well tolerated and resulted in a stable disease rate of approximately 33% in the evaluable patients. The Phase 1 study was not designed to pre-screen CEACAM-1 levels on tumor tissue. Furthermore, in this Phase 1 study, no PD-1 inhibitor was tested in combination with CM24. And as noted, the doses used in the aforementioned study were below those required to reach target saturation as determined by pharmacokinetic evaluations.

Manufacturing

We have entered into a master development services agreement with Rentschler Biopharma SE in Germany ("Rentschler"), pursuant to which Rentschler shall manufacture CM24 batches for clinical studies for a total amount of $6.4 million over a period of two years. Rentschler manufactured and provided the initial batch, and it is expected to manufacture the second (and final) batch in the near future. Pursuant to the agreement, we entered into a Quality Agreement with Rentschler.

Oncology Segment - NT219

NT219 is a small molecule that presents what we believe is a new concept in cancer therapy by inhibiting two oncology-related pathways, namely the IRS 1 and 2 and STAT3 pathways. The NT219 technology has been tested in a number of PDX models where biopsies from patients are implanted into mice and used to test various cancer drugs. In such models, NT219, alone and in combination with several approved oncology drugs, displayed potent anti-tumor effects and increased survival in experimental animals harboring various cancers by preventing the tumors from developing resistance to approved cytotoxic, immune-oncologic, and targeted drug treatments, and by re-sensitizing tumors to the approved drugs even after resistance has been acquired.

Background on Cancer Drug Resistance

The following are high-level summaries of the therapeutic areas we are currently investigating for NT219:

Solid malignancies (e.g., pancreatic, head and neck, colon and non-small cell lung cancer). According to the Journal of Oncology Practice, in 2020 roughly one in every 19 people worldwide would either be diagnosed with a solid tumor or be a cancer survivor. According to the American Cancer Society, lung, pancreatic, and colon malignancies have high mortality rates and poor five-year survival prognosis. Novel, emerging therapeutic approaches for targeting solid tumors are being developed and tested.

Tumor Resistance to Cancer Therapies. Resistance to chemotherapy and to targeted therapies is a major problem facing oncology. The mechanisms of resistance to 'classical' cytotoxic chemotherapeutics and to therapies that are designed to be selective for specific target proteins share many features, such as alterations in the drug target, activation of pro-survival pathways and ineffective induction of cell death.

Evidence suggests that among other mechanisms of resistance, inhibition of central oncological target kinases such as EGFR, MEK and mutated-BRAF could trigger feedback activation of STAT3 and IRS-to-PI3K/AKT, major survival pathways that bypass (prevent) the anti-cancer effects of various drugs.

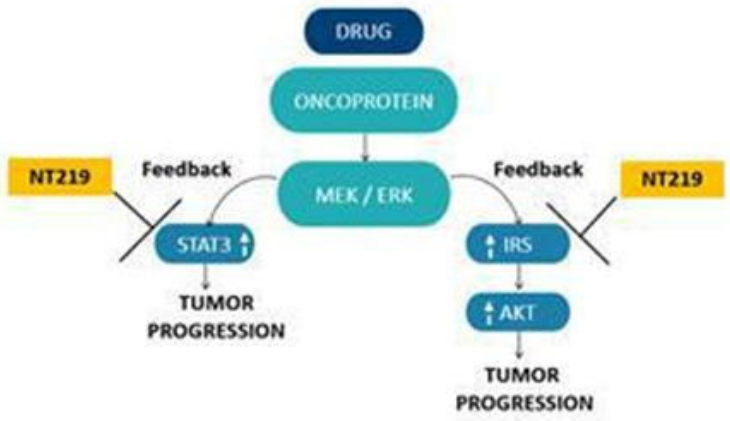
IRS. Insulin Receptor Substrate (IRS) is a junction protein that mediates various mitogenic and anti-apoptotic signals mainly from Insulin-like Growth Factor-1 Receptor (IGF1R) and Insulin Receptor (IR), but also from other oncogenes such as v-Src and ALK-fusion proteins. IRS expression is often up-regulated in human tumors, such as prostate, pancreatic, liver, renal and ovarian cancer. Resistance to several anti-cancer therapies (e.g., inhibitors of EGFR, MEK, mutated-BRAF, mTOR, as well as cytotoxic chemotherapy) may be mediated by IRS up-regulation, as demonstrated in peer reviewed research articles published in scientific journals.

STAT3. Signal Transducer and Activator of Transcription 3 (STAT3) plays crucial roles in several cellular processes such as cell proliferation and survival and has been found to be aberrantly activated in many cancer types (such as NSCLC, head and neck cancer, pancreatic cancer and many others). Much research has explored the leading mechanisms for regulating the STAT3 pathway and its role in promoting tumorigenesis. Evidence suggests that feedback activation of STAT3 plays a prominent role in mediating drug resistance to a broad spectrum of targeted cancer therapies and chemotherapies (such as inhibitors of EGFR, MEK, ALK, as well as 5FU, oxaliplatin and SN-38).

Mechanism of Action

The NT219 therapeutic candidate is a small molecule that we believe presents a new concept in cancer therapy, acting as a dual inhibitor of IRS1 and IRS-2 and STAT3, which putatively play major roles in oncogenesis and cancer drug resistance. While targeted anti-cancer drugs inhibit the "ON" signal, NT219 activates the "OFF" switch, leading to the degradation of IRS-1 and IRS-2, altering STAT3 phosporylation, and extensively blocking major oncogenic pathways.

IRS down-regulation can be mediated by several oncogenic pathways (EGFR, MAPK, mTOR, etc.). Blockade of these pathways by various drugs, could inhibit serine phosphorylation of IRS, leading to the activation of IRS to AKT survival bypass. Therefore, degradation of IRS1/2 by NT219 could potentially prevent resistance and prolong the tumor's response to various targeted drugs, as depicted below:



There have been reports in peer reviewed academic literature describing the involvement of Insulin-like Growth Factor-1 Receptor (IGF1R) up-regulation in drug-resistance. In these cases, blockage of IGF1R direct substrates, IRS1/2, by NT219 could potentially overcome drug resistance.

The same principal is true for STAT3. Feedback activation of STAT3 is a common resistance mechanism to many targeted cancer therapies (such as the inhibitors of EGFR, MEK, HER2) and cytotoxic chemotherapies. Combining these cancer therapies with NT219, which disrupt this feedback mechanism, could potentially enhance cell death and delay resistance, suggesting a co-treatment strategy that may be broadly effective in oncogene-addicted tumors.

Degradation of IRS proteins and blockage of STAT3 by NT219 could potentially prevent resistance to multiple anti-cancer drugs, extend the duration of effective drug treatment, and restore drug sensitivity in resistant tumors.

NT219 has high affinity and selective binding to its target proteins. NT219 binds covalently to Insulin Receptor Substrates (IRS) 1/2 and with low nano-molar affinity to the Signal Transducer and Activator of Transcription 3 (STAT3). Data from preclinical work showed that a short exposure of cancerous cells to NT219 was sufficient to trigger irreversible shutdown of these pathways, resulting in a long-term anti-cancer effect.

Preclinical results

In pre-clinical studies, NT219, in combination with several approved cancer drugs, displayed potent anti-tumor effects and increased survival in various cancers by preventing the tumors from developing drug resistance and restoring sensitivity to the drugs after resistance is acquired. NT219 has been tested in a number of PDX models where biopsies containing human primary cancer cells were transplanted into mice and then used to test various cancer drugs. NT219 has shown efficacy in various PDX models originated from head and neck, cancer, non-small cell lung cancer (NSCLC), sarcoma, melanoma, pancreatic, and colon cancers.

Efficacy of NT219 was demonstrated in combination with three major classes of oncology drugs:

1) Antibodies such as the anti-epidermal growth factor receptor (EGFR) antibody (Erbitux) and the immuno-oncology anti-PD1 antibody (Opdivo, Keytruda);

2) Kinase Inhibitors such as blockers of EGFR (Tagrisso, Tarceva), MEK (Mekinist), Mutated BRAF (Zelboraf), and mTOR (Afinitor); and

3) Chemotherapy agents such as gemcitabine (Gemzar), 5FU, and Oxaliplatin.

Clinical Plan

The clinical development strategy will parallel the preclinical studies, particularly with respect to the STAT3 and IRS/AKT pathway inhibition/s, which have been characterized as a putative *sine qua non* for the resistance phenotype. Moreover, the tumor types to be initially addressed also reflect the MEK/ERK pathway, and in particular, those tumors which functionally have shown dependence or driver mutations with respect to *erb-b* pathways. However, within the context of the preclinical studies that have been performed, there is also evidence of single agent activity noted with NT219, and this needs to be appreciated within the clinical development plan.

NT219 FIH studies need to consider primarily safety, particularly since the MOA relates to dual inhibition mechanisms. Within the context of single agent activity, it has been noted that in a variety of studies NT219 may have effect. As such, standard criteria in Phase 1 should be used to assess the agent in this monotherapy context, primarily with respect to safety, and evidence for a signal of biologic relevance.

As a result, the FIH Phase 1 study, which we commenced in the second half of 2020, will evaluate single agent NT219 as a dose escalation, in patients with advanced cancer. Patients will be unselected for this component of the trial (deemed Part A) and will be evaluated for safety as the primary endpoint, and efficacy as a secondary endpoint. The escalation will take the form of a 3+3 standard design, and a course of therapy will be four weeks. Patients will be administered NT219 weekly.

Upon achieving data on the third (of five) dose level, a separate arm of the study will be opened. This is the combination arm, administering NT219 with cetuximab (Part B). In this arm, patients with advanced cancer, who are eligible for cetuximab therapy (e.g., SCCHN and CRC), will receive a combination of the drugs, with NT219 being administered, followed by cetuximab, in a similar course of four weeks. The combination will be evaluated in a similar 3+3 design, always at a lower dose than that administered as a single agent, until/unless Part A completes the highest dose planned. These two parts of the study will provide information regarding the safety of NT219 as a single agent and in combination with cetuximab, including the determination of the maximal tolerated dose (MTD), as well as preliminary efficacy of NT219 as a single agent and in combination with cetuximab. It may also provide the impetus for the expansion of the study into a given indication, either as single agent or in combination.

We will commence the third portion (Part C) of the study subsequent to completion of Part B. Part C will include the administration of NT219 at its recommend Phase 2 dose in combination with standard dose cetuximab in patients with recurrent/metastatic squamous cell carcinoma of the head and neck (SCCHN). This part of the study will evaluate preliminary efficacy and safety in a larger cohort of patients. The planning of the Phase 2 studies will be a function of the data from FIH studies. Currently, there is evidence suggesting myeloproliferative neoplastic disease, as well as colorectal cancer should be assessed as monotherapy in the future. Similarly, based on *erb-b* pathway relevance, as well as data on the relevant inhibition of the dual pathways being evaluated, besides SCCHN, NSCLC, pancreatic cancer, and melanoma are also candidates for which we are planning future Phase 2 studies.

Competitive Oncology Drugs in Development that Target IRS1/2 or STAT3

While we are not familiar with other molecules which act as dual inhibitors of both IRS1/2 and STAT3, or lead to degradation of IRS1/2, and which are in late stage of development, there are several therapeutic candidates in development which target either upstream target of IRS1/2 as Insulin Like Growth Factor 1 Receptor (IGF1R), such as dalotuzumab (a recombinant humanized monoclonal antibody, developed by Merck & Co for metastatic breast cancer), or target STAT3 such as napabucasin (which is developed by Dainippon Sumitomo and designed to inhibit cancer stem cell pathways), which are currently in Phase 3 clinical trials for metastatic pancreatic and colon cancers. There are also other therapeutic candidates that target these pathways, which are mostly in early stage of development.

Pain and Hypertension Segment - Consensi

Background on Osteoarthritis and Hypertension

Numerous factors influence the drug market, including the aging of the general population. As life expectancy increases, we expect that demand will increase for innovative drugs that treat diseases related to the elderly, such as osteoarthritis and hypertension.

Osteoarthritis

Arthritis means joint inflammation. The term is used to describe the pain, stiffness and/or swelling in the joints of the body where one or more bones are joined by ligaments. A normal joint provides a smooth surface enabling adjacent bones to move and glide on each other during normal motion. In contrast, an arthritic joint is one that may have varying degrees of inflammation and possibly destruction of the joint cartilage. These destructive changes preclude normal motion and cause pain.

The most common type of arthritis is called osteoarthritis and is more common with advancing age. People with osteoarthritis usually have joint pain and a decreased range of joint movement. Unlike some other forms of arthritis, osteoarthritis affects only the joints. This condition is also sometimes called degenerative joint disease. Osteoarthritis primarily affects the joint cartilage. Healthy cartilage allows bones to glide over one another and absorbs energy from the shock of physical movement. However, with osteoarthritis, the surface layer of cartilage breaks down and wears away. This allows the bony surface of the different bones under the cartilage to rub together, causing, pain, swelling, and loss of motion of the joint. Over time, affected joints may lose their normal shape. Also, bone spurs, small growths called osteophytes, may grow on the edges of the joint further impairing joint function. Thus, bits of bone or cartilage can break off and float inside the joint space, causing more pain and possible damage.

Osteoarthritis in the younger population is usually caused by traumatic injuries to the joints. In contrast, in the older population it is a more of a chronic degenerative disease process. The main symptom of osteoarthritis is pain that appears gradually, worsens with exertion, and is transiently relieved by rest.

The pain caused by osteoarthritis is described by patients as a deep pain or a burning sensation related to the joint tissues of the affected area. Osteoarthritis mainly affects the cartilage and disrupts the structural balance in the cartilage of the joint, causing the cartilage cells to increase production of new raw materials required to create cartilage, but concurrently produce enzymes that digest the cartilage.

Osteoarthritis is one of the most common diseases worldwide causing physical disabilities in adults. According to the Centers for Disease Control and Prevention (CDC) an estimated 22.7% (54.4 million) of US adults (civilian, non-institutionalized US adult population aged 18 years or older) had doctor-diagnosed arthritis, with significantly higher age-adjusted prevalence in women (23.5%) than in men (18.1%). Arthritis prevalence increased with age. Studies have shown that approximately 44% of patients who suffer from hypertension are also diagnosed with osteoarthritis.

The pharmaceuticals used for treating osteoarthritis include a range of drugs. The particular choice of treatment is made according to the disease severity. These can range from acetaminophen for cases of milder severity, to diclofenac, naproxen, and celecoxib for moderate severity, up to treatment with narcotics for the most severe cases.

Various non-pharmacological treatments are intended to relieve the pain caused by the disease and to preserve and improve joint function. Among these treatments are changes in the patient's lifestyle, namely diet, physiotherapy and exercise. The objectives of these treatments are to strengthen the muscles adjacent to the joints and increase their ranges, thereby reducing body weight, and decreasing the loads on the weight carrying joints to subsequently reduce the intensity of the pain.

In some cases, the conservative non-pharmacological treatments are not sufficiently helpful. In such cases, patients typically request medical treatment. Common medical treatments are the use of analgesics, such as NSAIDs, which include enzyme inhibitors, such as COX-2. NSAIDs treat inflammation by inhibiting enzymes responsible for the initiation of the development of inflammation and subsequent pain. COX-2 enzyme inhibitors are non-steroidal drugs that treat inflammation by directly inhibiting COX-2, an enzyme responsible for the development of inflammation and subsequent pain but do not target the COX-1 enzyme. Targeting selectivity for COX-2 reduces the risk of peptic ulceration, and is the main advantage of celecoxib, rofecoxib and other members of this drug class over non-COX-2 selective NSAIDs.

After several COX-2 inhibiting drugs were approved for marketing, data from clinical trials revealed that COX-2 inhibitors caused a significant increase in heart attacks and strokes, with some drugs in the class possibly having worse risks than others. See "Business - Our Therapeutic Candidates – Competitive Treatments for Pain Caused by Osteoarthritis".

A typical osteoarthritis treatment plan with these analgesics is as follows: (i) initial treatment of minor osteoarthritis will begin with use of drugs such as acetaminophen; (ii) in the event that acetaminophen treatment is not effective, the physician will proceed to treatments using NSAIDs, which will begin using drugs such as ibuprofen followed by naproxen and/or other NSAIDs (more than 20 types of drugs, including COX-2 enzyme inhibitors); (iii) in cases where treatment with these drugs is ineffective, the treatment will be direct injection of steroids into the affected joint; (iv) in cases where steroid injection is ineffective, treatment by injecting hyaluronic acid (HA) into the affected joint will be considered; and (v) in the event that all the aforementioned treatments fail, the patient may consider surgical replacement of the affected joint.

As noted above, NSAIDs, both over-the-counter and prescription are commonly taken to manage the pain of backache, osteoarthritis, rheumatoid arthritis, headache and other painful conditions. For example, according to a study commissioned by us from IMS Health, the largest vendor of U.S. physician prescribing data, between April 2015 and March 2016 there were 2,428,176 prescriptions for celecoxib dispensed in the U.S.

In July 2015 the FDA published a safety announcement requiring labeling for prescription NSAIDs to indicate that the risk of heart attack or stroke can occur as early as the first weeks of using an NSAID and that the risk may increase with longer use of the NSAID. In effect, the current warnings indicated on the labeling, in effect since 2005, has been strengthened as a result of a review by the FDA of a variety of new safety information on prescription and over-the-counter NSAIDs, including observational studies, a large combined analysis of clinical trials, and other scientific publications. These studies were discussed at a joint meeting of the Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee held in February 2014. As a result of its reviews of NSAIDs, the FDA has cautioned in the labeling of NSAIDs that combining an NSAID with antihypertensive drugs, including diuretics, beta blockers, ACE inhibitors, or angiotensin receptor blockers, may markedly diminish the efficacy of these antihypertensive drugs. Calcium channel blockers, such as amlodipine besylate, the anti-hypertensive component of Consensi, were not included in this labeling requirement.

Hypertension (High Blood Pressure)

According to its physiological definition, "hypertension" is an excessive pressure applied by the blood on the walls of the blood vessels. The term hypertension refers to excessive arterial blood pressure, which is the pressure in the arteries that propels blood to body organs.

The blood pressure is created as a result of the contraction of the cardiac muscle propelling blood into the arteries, which possess a limited capacity to store the blood. Blood pressure is measured in units of mercury (Hg) millimeters (mm Hg). Diagnosing hypertension in adults requires at least two measures on two different occasions. There are two blood pressure values:

- Systolic pressure is the peak pressure in the arteries measured in the cardiac cycle, during the contraction of the heart's left ventricle (systole); and

- Diastolic pressure is the lowest pressure point in the arteries measured when the heart's left ventricle is relaxing and there is no contraction of the heart (diastole).

In the past, hypertension was generally defined as a systolic blood pressure of greater than 140 mm Hg or a diastolic blood pressure of greater than 90 mm Hg. However, as discussed below, a recently halted NIH study may result in these designated values being set lower. As a result of these data, multiple entities, including the American College of Cardiology, have recommended that a patient's systolic blood pressure should be maintained at a level below 130 mm Hg, and their diastolic blood pressure maintained below 80 mm Hg.

The cause of hypertension in 95% of patients is unknown, and in these cases hypertension is defined as "essential hypertension". However, some studies postulate that genetic factors and environmental factors are involved in the initial development of hypertension. These factors include high salt consumption, obesity, excessive alcohol consumption, and probably mental and behavioral factors, which may be caused by various circumstances, including working in certain professions. Extreme hypertension may lead to functional disorders, and worsening health, while the affected person does not necessarily feel it and/or is aware of it. Therefore, hypertension is often referred to as the "silent killer".

The danger of hypertension is continuing damage to blood vessels in critical areas of the body, such as blood vessels in the heart, kidneys, eyes, and to the nerve tissue in the brain where any damage may cause a stroke. Moreover, damage to the blood vessels may cause blockage due to arteriosclerosis and lead to the tearing of the vessels. These complications may cause various diseases and even death.

Hypertension treatment methods focus on reducing the patient's blood pressure to normal values, thereby preventing the occurrence of complications in the long term. Even a small increase in blood pressure may cause significant cardiovascular problems. For example, it has been shown that any increase in blood pressure above a systolic value of 115 mm Hg is associated with an increased risk of suffering a cardiovascular death. This finding has been repeatedly replicated and it is now established that there is no safe level of blood pressure increase above of the "normotensive baseline value" of approximately 120 systolic and 70 diastolic. The documentation of a danger of any increase in blood pressure above a value of 120/70 was documented in September of 2015 in a large NIH sponsored clinical trial which enrolled over 9,000 patients ages 50 and older. This study also documented that patients ages 50 and older with systolic blood pressures greater than 120 had a greater rate of adverse cardiovascular events than did those whose systolic blood pressure was treated to levels below 120.

It has been recognized for many decades that hypertension requires treatment. Hypertension can be treated with many different classes of medications. These include diuretics, beta blockers, alpha blockers, calcium channel blockers, ACE inhibitors, angiotensin receptor antagonists and vasodilators. In general, these medications work by either relaxing blood vessels and thereby lowering the pressure in arteries, or by assisting the body in removing fluid and thereby decreasing the pressure inside of arteries.

Although drugs from each of the various classes of antihypertension medications are able to reduce blood pressure, there are marked differences in their side effects profiles. For example, the diuretics can result in kidney problems, while the beta blockers can slow the heart rate. It is therefore important for physicians carefully to select which antihypertension medications to prescribe for patients based upon the patient's other medical problems, including what concomitant medications they are receiving.

Blood pressure can undergo significant alterations when subjects are placed on various medications. For example, according to a May 2010 FDA Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee report published by the FDA, an increase of about 3.5 mm Hg was diagnosed following the use of naproxen, while the use of Celebrex causes an increase of about 2.5 mm Hg. In addition, in August 2011 the FDA issued a Safety Information release stating that co-administration of NSAIDs, including selective COX-2 inhibitors, with ACE inhibitors or with angiotensin II receptor antagonists, may result in deterioration of renal function, including possible acute renal failure, and that the antihypertensive effect of ACE inhibitors may be attenuated by NSAIDs. No such Safety Information release was issued with regard to calcium channel blockers, which is the anti-hypertensive used in our therapeutic candidates.

The FDA has also required warnings in the labeling of NSAIDs that adding diuretics or beta blockers to patients on NSAIDs can cause problems with the control of their blood pressure. Calcium channel blockers, such as amlodipine besylate, the anti-hypertensive component of Consensi, were not included in this labeling requirement.

Our Consensi Drug

Our FDA-approved drug Consensi is based on the generic substances celecoxib and amlodipine besylate. Celecoxib is the active ingredient in the branded drug Celebrex, a known and approved-for-use drug designed primarily to relieve pain caused by osteoarthritis. Our combination is designed simultaneously to relieve pain caused by osteoarthritis and treat hypertension, which is one of the side effects of using NSAIDs for treating pain caused by osteoarthritis. Consensi is based on our belief that the added anti-hypertensive drug will decrease the side effect of increased hypertension typically caused by the use of NSAIDs alone.

To date, other than our recently approved Consensi product, no combination drug exists that offers the combined treatment of pain caused by osteoarthritis and hypertension. We therefore believe that Consensi potentially holds significant advantages over the currently available drugs in the market, due to the fact that the drug treatment of osteoarthritis together with hypertension eases the burden of the treatment process for patients by providing the ability to use one drug instead of multiple drugs concurrently, thereby increasing the patients' ease of adherence to the required treatment.

Consensi is a fixed-dose combination product based on two generic substances (celecoxib and amlodipine besylate), the effectiveness and safety of which has been separately proven for each, and which is intended to enable the concurrent treatment of pain caused by osteoarthritis, and hypertension. We anticipate that treating the symptoms of hypertension and osteoarthritis will lower blood pressure and by so doing, will reduce the risk of fatal and nonfatal cardiovascular events such as strokes or myocardial infarctions. Consensi is available in tablets and is to be administered orally once per day. Consensi tablets are formulated according to the following strengths (amlodipine/celecoxib): 2.5 mg/200 mg, 5 mg/200 mg, and 10 mg/200 mg tablets.

For the development of Consensi, we performed a double blind, placebo controlled, Phase 3 clinical trial from June 2014 through November 2015 testing the decrease of hypertension in patients receiving the two components of our Consensi therapeutic candidate. This trial was performed in the U.K. in four groups of twenty-six (26) to forty-nine (49) patients (a total of 152 patients), with each patient treated over a total period of two weeks. Group One was treated with the two components of Consensi (celecoxib and amlodipine besylate), Group Two was treated with a standard drug available in the market for treating hypertension (amlodipine besylate, one of the components of Consensi), Group Three was treated with celecoxib only, and Group Four received a double placebo.

The purpose of the trial was to show that a combination of the two components of Consensi, as demonstrated in Group One, lowered blood pressure by at least 50% as compared to the reduction in blood pressure in patients in Group Two (treatment with amlodipine besylate only). We were not required by FDA to demonstrate or measure efficacy in treatment of pain caused by osteoarthritis. Group Three and Group Four were included for control purposes and would not be considered in evaluating the primary efficacy endpoint. The trial was conducted with over-encapsulated off-the-shelf drugs. The trial's interim results demonstrated that the number of 152 patients treated was adequate to provide statistical validity and therefore, the results were final. These final results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with Consensi's two components, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

Additional data from the Phase 3 clinical trial of Consensi suggested beneficial effects on renal (kidney) function, as compared to negative effects on renal function caused by other NSAIDS.

Subsequently, we completed a Phase 3/4 clinical trial designed to validate and better quantify these potential beneficial renal effects. The trial was designed to explain the synergistic antihypertensive effect, where the reduction in diastolic blood pressure demonstrated with the components of Consensi was greater than that observed with amlodipine besylate alone at certain times of the day. Accordingly, we conducted a double blind, placebo controlled, clinical trial intended statistically to demonstrate Consensi's effects on renal and vascular function, while providing us with data with respect to Consensi in addition to the data of the Phase 3 clinical trial, by utilizing a primary efficacy end-point in the renal function clinical trial comparable to that of the Phase 3 clinical trial. The primary efficacy endpoint of the trial was to show that Consensi lowers daytime systolic blood pressure by at least 50% of the reduction in blood pressure achieved in patients treated with amlodipine besylate only. Secondary endpoints included various parameters of renal function. In October 2017, we announced that Phase III/IV renal function clinical trial, successfully met its primary efficacy endpoint. Data from the Phase III/IV trial demonstrated that Consensi lowered systolic blood pressure a comparable amount to amlodipine besylate, thus meeting the trial's primary efficacy endpoint of achieving at least 50% of the amlodipine reduction (p=0.019). The study also demonstrated that treatment with Consensi led to a statistically significant reduction of serum creatinine, a marker of renal function, from its baseline value (p=0.0005). In contrast, neither amlodipine besylate nor placebo lowered creatinine to a statistically significant level. When comparing the effect of Consensi to amlodipine besylate in lowering creatinine, it was found that Consensi enhanced the creatinine reduction by an average of 102% over that achieved with amlodipine besylate alone, although there was a slight, but statistically insignificant, increase in the rate of edema in the Consensi treatment arm.

Consensi is based on two generic drugs (amlodipine besylate and celecoxib). Until December 2015 celecoxib was protected by patents held by Pfizer Inc. (Celebrex). The USPTO granted Pfizer a "reissue patent" covering methods of treating osteoarthritis and other approved conditions with celecoxib, the active ingredient in Celebrex. The reissued patent extended U.S. patent protection for Celebrex from May 30, 2014 to December 2, 2015.

We submitted the NDA for marketing approval of Consensi to the FDA in July 2017, and the FDA approved our NDA on May 31, 2018. Consensi was approved for patients suffering from hypertension and from osteoarthritis for whom treatment with amlodipine for hypertension and celecoxib for the treatment of osteoarthritis are appropriate.

In connection with our Consensi drug product, we are subject to post-marketing requirements and post-marketing commitments. Post-marketing requirements and post-marketing commitments are studies that sponsors conduct after FDA approval to gather additional information about a product's safety, efficacy, or optimal use. Post-marketing requirements are required studies, whereas a sponsor voluntarily commits to conduct post-marketing commitments. We are required by the FDA to comply with reporting requirements including but not limited to submitting serious unexpected adverse drug experiences no later than 15 calendar days from initial receipt of the information and also to provide a periodic report quarterly for the first three years of approval and then annual after the first three years. The FDA waived a requirement to conduct a pediatric assessment under the Pediatric Research Equity Act because Consensi is intended to treat indications that are rarely experienced in pediatric populations.

We also committed to conducting additional supplementary CMC studies on our Consensi drug product, including an elemental impurities assessment and a dissolution method and acceptance criteria development study. We were also required to perform validation for scaling up the manufacturing of Consensi by our manufacturer Dexcel., Ltd., or Dexcel. We performed these studies and validations in 2020.

In November 2018, we entered into a Product Manufacturing Agreement (the "Product Manufacturing Agreement"), as amended on May 17, 2020, with Dexcel, a global pharmaceutical company, which has been involved in the manufacture and marketing of more than 55 branded and generic products, pursuant to which Dexcel manufactured scale-up batches as well as validation batches of Consensi in anticipation of the launch of the drug in the U.S. by our U.S. distribution partner. The Product Manufacturing Agreement also provides for an ongoing supply of Consensi to our distribution partners. Dexcel previously manufactured Consensi for us under a Development Services Agreement, pursuant to which Dexcel developed the formulation for Consensi, conducted the subsequent stability testing and manufacturing scale-up in quantities adequate for submission of the NDA to the FDA.

In May 2020, we launched the U.S. commercial sales of Consensi, which is being sold in the U.S. by Burke Therapeutics.

The FDA required Important Safety Information for the Consensi product is as follows:

Important Safety Information (ISI) for Consensi

WARNING: RISK OF SERIOUS CARDIOVASCULAR and GASTROINTESTINAL EVENTS

See full prescribing information for complete boxed warning.

CONSENSI contains celecoxib, a nonsteroidal anti-inflammatory drug (NSAID), and amlodipine, a calcium channel blocker (CCB). NSAIDs can cause serious side effects, including:

- **Increased risk of a heart attack or stroke that can lead to death. This risk may happen early in treatment and may increase with duration of use.**
- **Do not take CONSENSI right before or after a heart surgery called a "coronary artery bypass graft" (CABG).**
- **Avoid taking CONSENSI after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.**
- **NSAID medications, like celecoxib, cause an increased risk of bleeding, ulcers, and tears (perforation) of the esophagus, stomach, and intestines, at any time during treatment, which can occur without warning and may cause death. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.**

What is the most important information I should know about Consensi?

Consensi contains celecoxib, a nonsteroidal anti-inflammatory drug (NSAID), and amlodipine, a calcium channel blocker (CCB). NSAIDs can cause serious side effects, including:

- **Increased risk of a heart attack or stroke that can lead to death.** This risk may happen early in treatment and may increase:
  - with increasing doses of NSAIDs
  - with longer use of NSAIDs

Do not take Consensi right before or after a heart surgery called a "coronary artery bypass graft" (CABG).

Avoid taking Consensi after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

- **Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach, and intestines:**
  - anytime during use
  - without warning symptoms
  - that may cause death

The risk of getting an ulcer or bleeding increases with:

- o past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
- o taking medicines called "corticosteroids", "antiplatelet drugs", "anticoagulants", "selective serotonin reuptake inhibitors (SSRIs)", or "serotonin norepinephrine reuptake inhibitors (SNRIs)"
- o increasing doses of NSAIDs
- o longer use of NSAIDs
- o Smoking
- o drinking alcohol
- o older age
- o poor health
- o advanced liver disease
- o bleeding problems

You should not take other medicines that contain NSAIDs or salicylates during treatment with Consensi because of increased risk of stomach problems. Taking other medicines that contain NSAIDs or salicylates during treatment with Consensi will not provide increased relief of symptoms of osteoarthritis.

Consensi should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

Who should not take Consensi?

Do not take Consensi:

- if you are allergic to amlodipine, celecoxib or any of the inactive ingredients in Consensi.
- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- right before or after heart bypass surgery.
- if you have had an allergic reaction to sulfonamides.

Before taking Consensi, tell your healthcare provider about all your medical conditions, including if you:

- have heart problems.
- have liver or kidney problems.
- have asthma.
- are pregnant or plan to become pregnant. Talk to your healthcare provider if you are considering taking Consensi during pregnancy. **You should not take Consensi after 29 weeks of pregnancy.**
- are breastfeeding or plan to breastfeed. Consensi can pass into your breast milk. It is not known if Consensi will harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take Consensi.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements. Consensi and some other medicines can interact with each other and cause serious side effects. **Do not start taking any new medicine without talking to your healthcare provider first.**

What are the possible side effects of Consensi?

Consensi can cause serious side effects, including:

- liver problems, including liver failure
- worsening chest pain (angina) or heart attack, particularly in people with severe obstructive coronary artery disease
- heart failure
- swelling of your arms, legs, hands and feet (peripheral edema) is common with Consensi but can sometimes be serious.
- kidney problems, including kidney failure
- increased potassium levels (hyperkalemia)
- life-threatening allergic reactions
- life-threatening skin reactions
- low red blood cells (anemia)

See "What is the most important information I should know about Consensi?" for further detail regarding serious side effects.

Your healthcare provider will monitor your blood pressure and do blood tests to check you for side effects during treatment with Consensi.

Consensi may cause fertility problems in females that is reversible when treatment with Consensi is stopped. Talk to your healthcare provider if this is a concern for you.

The most common side effects of Consensi include:

- swelling of the arms, legs, hands, and feet
- joint swelling
- dizziness
- stomach pain
- Diarrhea
- Heartburn
- headache
- frequent urination
- hot or warm feeling in your face (flushing)
- gas
- tiredness
- extreme sleepiness

Get emergency help right away if you get any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop taking Consensi and call your healthcare provider right away if you get any of the following symptoms:

- Nausea
- more tired or weaker than usual
- Diarrhea
- Itching
- indigestion or stomach pain
- flu-like symptoms
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- unusual weight gain
- your skin or eyes look yellow
- skin rash or blisters with fever
- swelling of the arms, legs, hands and feet

These are not all the possible side effects of Consensi.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**. You may also report side effects to Burke Therapeutics, LLC at 1-866-275-1264.

Please see Full Prescribing Information, including BOXED WARNING, and Medication Guide.

Competitive Treatments for Pain Caused by Osteoarthritis

The competition for Consensi is expected to come from the oral anti-arthritic market, or more specifically the traditional non-selective NSAIDs (such as naproxen and ibuprofen), traditional NSAID/gastroprotective agent combination products or combination product packages (such as Vimovo, Arthrotec, Prevacid and NapraPAC™) and the only COX-2 inhibitor available in the U.S. market, Celebrex (including generic versions of Celebrex). In 2017 global sales of Celebrex (not including generic versions of Celebrex) were $775 million out of which $164 million were recorded in the US, $28 million in Europe, and $583 million in the rest of the world.

Due to the voluntary withdrawal of Vioxx by Merck & Co. in September 2004, the FDA ordered the withdrawal of Bextra by Pfizer and issued a Public Health Advisory in April 2005, requiring manufacturers of all prescription products containing NSAIDs to provide warnings regarding potential adverse cardiovascular events as well as life-threatening gastrointestinal events associated with the use of NSAIDs. Moreover, subsequent to an FDA advisory committee meeting in February 2005 that addressed the safety of NSAIDs, and, in particular, the cardiovascular risks of COX-2 selective NSAIDs, the FDA has indicated that long-term studies evaluating cardiovascular risk will be required to approve new NSAID products that may be used on an intermittent or chronic basis. We believe that Consensi has a competitive advantage over other drugs in the market because, as a COX-2 inhibitor, it has limited gastrointestinal side effects, and due to the addition of amlodipine besylate it is designed to address existing hypertension and the cardiovascular side effects of NSAIDs.

License Agreement for Territory of South Korea

On March 8, 2017, we announced that the Company signed a definitive License Agreement for Consensi for the territory of South Korea with Kuhnil Pharmaceutical Co., Ltd. (“Kuhnil”), a South Korean pharmaceutical company. Upon receipt of marketing authorization in South Korea, Kuhnil will have the exclusive right and license to manufacture, distribute and sell Consensi in South Korea. Kuhnil will be responsible for seeking regulatory approval for Consensi in South Korea. Under the terms of the license agreement, we are entitled to receive milestone payments upon achievement of certain predefined regulatory milestones, as well as double digit royalties in a range between ten and twenty percent of net sales. The initial term of the definitive agreement with Kuhnil is for ten years from the date of first commercial sale and shall automatically renew for an additional one-year term. The filling for marketing authorization with the South Korean regulatory authorities is pending, and commercial launch in South Korea is now estimated to take place in 2022.

Commercialization Agreement for China

In May 2018 we signed a definitive License, Development and Commercialization Agreement for Consensi for the territory of China with Hebei Changshan Biochemical Pharmaceutical Co., Ltd. (Changshan Pharma), a Chinese public company traded on the Shenzhen Stock Exchange. Upon receipt of marketing authorization in China, Changshan Pharma will have the exclusive right and license to import, manufacture, distribute and sell Consensi in China, Taiwan, Hong Kong and Macao. Changshan Pharma will be responsible for seeking marketing authorization in China for Consensi in China. Under the terms of the agreement, we are entitled to receive up to an aggregate of $3.5 million, of which $1.0 million was paid to us following FDA approval of Consensi and $2.5 million will become payable upon achievement of certain regulatory milestones in China; up to an aggregate of $6.0 million for predefined commercial milestones; and up to 12% royalties on net sales. The initial term of the definitive agreement with Changshan Pharma is for ten years from the date of first commercial sale and shall automatically renew for additional one-year terms. Changshan Pharma has not yet submitted the Chinese NDA.

Commercialization Agreement for the United States

In January 2019, we entered into an exclusive marketing and distribution agreement with Coeptis for the commercialization of Consensi in the U.S. market. The agreement was amended in July 2019 and in October 2019. Under the terms of the amended agreement, we will receive 20% in royalties on net sales of Consensi with minimum royalties of $4.5M over three years. In addition, we are entitled to receive up to $99.5 million in milestone and reimbursement payments, of which $3.5 million was already received and $96 million is subject to certain pre-defined commercial milestones. The agreement is for a term of 15 years and may be extended for additional two-year terms, and includes customary provisions, as well as certain residual rights and obligations of the parties following termination.

Manufacturing

In November 2018, we entered into the Product Manufacturing Agreement, as amended on May 17, 2020, with Dexcel, pursuant to which Dexcel manufactured scale-up batches as well as validation batches of Consensi, and also provides for ongoing supply of Consensi to our distribution partners. Under the agreement Dexcel manufactures Consensi in three dosage forms. Pursuant to the Product Manufacturing Agreement we also entered into a Quality Agreement with Dexcel and Coeptis.

Intellectual Property

Patents, trademarks and licenses and market exclusivity

Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on our trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position. We vigorously defend our intellectual property to preserve our rights and gain the benefit of our technological investments. Our business is not dependent, however, upon any single patent, trademark or contract. See "Item 3. Key Information – D. Risk Factors – Risks Related to Intellectual Property".

Oncology Segment - FameWave

Patents

FameWave's patent and patent application portfolio, covering the entire CEACAM1 antibody termed CM24 and other antibodies and uses thereof, includes five patent families, covering anti CEACAM1 antibodies and their uses in the treatment of cancer diseases.

- *Patent Family 1* relates to anti-human CEACAM1 antibodies, hybridoma cells producing these antibodies and methods of using the antibodies. United States patents as well as European counterparts were granted, as well as patents in Australia, China, Hong Kong, Israel, Japan, Korea and Russia, all of which have a maximum term of April 28, 2030. The European patents were validated in France; Germany; Ireland; Italy; The Netherlands; Poland; Spain; Switzerland; and United Kingdom. A patent application in Canada was allowed and is expected to be granted shortly, and another patent application is pending in Brazil.

- *Patent Family 2* relates to method of diagnosing melanoma or monitoring progression of melanoma, the method comprising determining a level of human CEACAM1 on isolated lymphocytes of a human subject in need thereof, wherein an upregulation of said level of CEACAM1 above a predetermined threshold is indicative of melanoma or stage thereof in said subject. Patents were granted in Israel and Europe. The European patent was validated in United Kingdom, Ireland, The Netherlands, Germany, Spain, Italy, France and Switzerland. All granted patents have a maximum term of July 20, 2030.

- *Patent Family 3* relates to antibodies (in particular chimeric antibodies) as well as molecules having at least the antigen-binding portion of an antibody against the human protein CEACAM1. A United States patent as well as European national phase counterparts were granted and divisional applications are pending. The European patent was validated in Germany, France, Spain, Italy, United Kingdom, Ireland, The Netherlands, Poland and Switzerland. Patents were also granted in China, Hong Kong, India, Israel, Japan, Korea and Russia. The patents of this family have a maximum term of October 9, 2032, except for the U.S. patent that has a maximum term of May 22, 2030. Patent applications are also pending in Brazil and Canada.

- *Patent Family 4* relates to compositions comprising anti-human CEACAM1 antibodies, compositions comprising antibodies capable of inhibiting or blocking the interaction between PD-1 and its ligands, and methods for their combined use in treating cancer. Patents have been granted in the United States, Europe, Canada, China, Mexico and Russia. The European patent was validated in United Kingdom, Ireland, The Netherlands, Germany, Spain, Italy, France, Switzerland and Poland. These patents have a maximum term of November 24, 2034. Patent applications are pending in Brazil, India and Japan.

- *Patent Family 5* relates to humanized antibodies, capable of specific binding to human CEACAM1 molecules containing human-to-murine back-mutations in non-CDR variable regions, and their encoding polynucleotide sequences. Patents have been granted in the United States, Europe, China, Israel and Mexico with a maximum term of April 26, 2035 The European patent was validated in United Kingdom, Ireland, The Netherlands, Germany, Spain, Italy, France, Switzerland and Poland. Applications are allowed in Eurasia and Japan, divisional applications are pending is Europe, United States and Mexico and national phase applications are pending in Brazil, Canada, India and Korea.

License Agreement with Tel HaShomer

On April 16, 2012, cCAM entered into a license agreement with THM and Ramot at Tel Aviv University Ltd. ("Ramot"), which was effective as of May 25, 2010, pursuant to which THM and Ramot granted cCAM a worldwide, royalty-bearing, exclusive license to develop, manufacture, produce, market and sell any biopharmaceutical product and/or diagnostic product using patents and inventions owned by THM and Ramot in connection with uses of the glycoprotein CEACAM1 (the "THM License Agreement"). The THM License Agreement was subsequently amended in 2013 and in 2015.

In conjunction with the closing of the reversion agreement amongst MSD, cCAM and FameWave, the parties executed an Assignment and Assumption Agreement by and between FameWave and cCAM (an MSD subsidiary), according to which cCAM assigned to FameWave all its rights, title and interest in, to and under the License Agreement, which Assignment and Assumption Agreement was countersigned by each of Ramot and THM, as a condition for closing of such reversion agreement (defined as the transfer of those certain assets from cCAM and MSD to FameWave).

Under the terms of the THM License Agreement, THM and Ramot retain ownership of the licensed information (defined as the patents and inventions licensed under the License Agreement). However, FameWave will own all rights to any data and information created and/or generated by cCAM and subsequently by FameWave, whether or not its development is based on the licensed information, including any proprietary intellectual or industrial property rights. FameWave and THM and/or Ramot will jointly own all rights to any data and information mutually created and/or generated by FameWave together with THS/Ramot/Sheba employees or agents, or TAU's students, employees or agents.

FameWave has the right to grant sub-licenses to third parties in accordance with the terms set forth in the THM License Agreement. THM and Ramot retain the right to use the licensed information solely for academic and/or scholarly purposes, provided that such use does not harm and/or expose FameWave's confidential information.

In consideration for the license grant, FameWave agreed to pay to THM an annual license fee, royalties based on a percentage of "Net Sales", a percentage of the sales-based sublicense fees, and a percentage of the sublicense fees. Additionally, FameWave has undertaken to pay certain milestone payments and a percentage of all consideration received by FameWave or its shareholders as a result of or in connection with an exit event (as defined). Finally, THM also received an assignable warrant to purchase, upon the closing of an IPO of FameWave, ordinary shares of FameWave, at a price equal to a certain percentage of the forecast initial market value of FameWave for each share as was determined, prior to the IPO, for the purpose of the IPO.

FameWave agreed to bear sole responsibility and payment obligations for any damage caused by or on behalf of FameWave or any sublicensee as a result of or in connection with the THM License Agreement and/or the exercise of the license. FameWave is also required to indemnify THM, Sheba, TAU and Ramot, and their respective employees, agents and representatives, from and against any and all loss, liability, claims, damages and expenses (including legal costs and attorneys' fees) of whatever kind or nature by a third party that arise out of and/or result from the THM License Agreement and/or the exercise of the license, or to the extent that they are based on a claim that the licensed information, the products or other material produced by FameWave infringes any third party's intellectual property rights including copyright, trade secret, patent, or trademark.

According the THM License Agreement, FameWave undertook to develop, manufacture, sell and market products pursuant to the milestones and time schedule attached to the THM License Agreement. FameWave is required to bear all costs and fees incurred prior to and during the term of the THM License Agreement, in connection with the preparation, filing, maintenance, prosecution and the like of any patents deemed necessary to protect the licensed information, and in case of third party infringement, FameWave is obligated, at its expense, to institute, prosecute and control any action or proceeding with respect to such infringement.

THM is entitled to appoint an observer to FameWave's board of directors who has all the rights of any other director of FameWave save for the right to vote. To date, THM has not acted on this right.

FameWave has agreed to purchase and maintain, at its own expense, insurance which covers its liability pursuant to the THM License Agreement, in its name and naming the indemnified parties as additional insured parties.

The term of the THM License Agreement continues on a product-by-product and country-by-country basis, until the later of (i) the date of expiry of the last of the licensed patents in such country; or (ii) the expiry of a period of 15 years from the first commercial sale in such country.

THM and Ramot may terminate the THM License Agreement and/or the license if (i) the first commercial sale of the product has not been made within two years from FDA or CE marketing approval; (ii) FameWave breaches any of its obligations under the THM License Agreement and such breach is not cured within 60-90 days, depending on the materiality of the breach; (iii) FameWave breaches any of FameWave's obligations under the THM License Agreement, and such breach remains uncured for 90 days after written notice; (iv) FameWave becomes insolvent, or petitions are filed against it under insolvency laws; (v) FameWave has ceased to carry on business as an ongoing concern; or (vi) FameWave has challenged, challenges, or causes any third party to challenge, the intellectual property rights or other rights or THM or Ramot to the licensed information anywhere in the world.

Upon termination of the THM License Agreement, other than due to expiration of the THM License Agreement, all rights granted to FameWace revert to THM and Ramot and FameWave will not be entitled to make any further use in the licensed information. The THM License Agreement is governed by the laws of the State of Israel.

Oncology Segment – TyrNovo

Patents

TyrNovo's patent and patent application portfolio, covering NT219 and other compounds, includes five patent families, covering compounds that modulate protein kinase signaling and their use in treatment of protein kinase related disorders, including cancer and neurodegenerative disorders.

- *Patent Family 1* relates to compounds modulating the insulin-like growth factor receptor signaling and methods of using these compounds as chemotherapeutic agents for the treatment of protein kinase related disorders, in particular cancer. Patents were granted in Europe and the United States, and have a maximum term of December 4, 2027, April 2, 2028, respectively. The European patent was validated in France, Germany, Switzerland and the United Kingdom.

- *Patent Family 2* also relates to compounds modulating the insulin-like growth factor receptor signaling and methods of using these compounds as chemotherapeutic agents for the treatment of protein kinase related disorders, in particular cancer, and specifically discloses and claims NT219. Patents were granted in Europe and Israel, and have a maximum term of June 7, 2029, and in the United States, with a maximum term of April 2, 2028. The European patent was validated in France, Germany, Italy, The Netherlands, Spain, Switzerland, and the United Kingdom.

- *Patent Family 3* relates to compounds having a benzo[e][1,3]thiazin-7-one core and methods of using these compounds as chemotherapeutic agents for the treatment of protein kinase related disorders, in particular cancer. Patents were granted in Europe and the United States, with a maximum term of December 27, 2031, and April 9, 2032, respectively. The European patent was validated in France, Germany, Italy, The Netherlands, Spain, Switzerland, and the United Kingdom.

- *Patent Family 4* relates to combinations of the compounds disclosed in Patent Families 1-3, acting as dual modulators of Insulin Receptor Substrate (IRS) and signal transducer and activator of transcription 3 (STAT3), with various targeted drug classes (inhibitors of Epidermal Growth Factor Receptor (EGFR), mTOR; mitogen-activated protein kinase (MEK) or mutated B-Raf), as well as chemotherapeutic agents (Gemcitabine, 5-FU, Irinotecan and Oxaliplatin), and use of such combinations for the treatment of cancer. Patents were granted in Australia, China and Europe, and have a maximum term of February 4, 2036, and in the United States, with a maximum term of August 12, 2036. Patent applications are pending in Brazil, Canada, China, Europe, Israel, Japan, Korea and the United States. The European patent was validated in Switzerland, Germany, Spain, France, Great Britain, Ireland, Italy and The Netherlands.

- *Patent Family 5* relates to specific combinations of the compounds disclosed in Patent Families 1-3, with various antibodies against programmed cell death 1 (PD-1) protein and/or anti-programmed cell death protein 1 ligand (PD-L1). Patent applications are pending in Brazil, Canada, China, Europe, India, Israel, Japan, Korea, Mexico, Russia and the United States. Any patent issuing from these applications will have a maximum patent term of November 16, 2037.

On December 21, 2020, the University and BIRAD filed a statement of claim to the court against TyrNovo, the Company, its officers and others. In the claim, the petitioners allege that the University is the rightful owner of a patent owned by TyrNovo. The main remedy sought by the Petitioners is a declaratory relief under which the University is declared the owner of such patent. We plan to file our response in April 2021, when it is due. At this preliminary stage we are unable, with any degree of certainty, to make any evaluations or any assessments with respect to the probability of success or the scope of potential exposure, if any.

Exclusive License Agreement with Yissum

In August 2013, TyrNovo entered into a license agreement with Yissum, which was subsequently amended in April 2014 and March 2017, pursuant to which Yissum has granted TyrNovo an exclusive license (with the right to sublicense) for the development, use, manufacturing and commercialization of products using certain patents and know-how owned by Yissum and patent applications filed by Yissum in connection with unique inhibitors of the IGF-1R Pathway (the "Yissum License Agreement").

Under the terms of the Yissum License Agreement, Yissum shall retain the ownership of the Licensed Technology (as such term is defined therein). All rights in the results of the activities carried out by TyrNovo or third parties in the development of these products (and certain results obtained under material transfer agreements signed by TyrNovo and Yissum (the "TyrNovo MTAs")) shall be solely owned by TyrNovo (unless an employee of the Hebrew University of Jerusalem or each of its branches is an inventor of any of the patents claiming such results, in which case they shall be owned jointly by Yissum and TyrNovo). TyrNovo has the right to grant sub-licenses to third parties in accordance with the terms set forth in the Yissum License Agreement.

TyrNovo has agreed to pay Yissum a percentage of "net sales" as royalties and to pay Yissum a percentage of the income that it receives from granting sub-licenses to third parties. Additionally, in the event of an M&A prior to an IPO, TyrNovo will be required to pay Yissum a percentage of the proceeds received under such M&A. In the event of an IPO, then prior to the closing of such IPO TyrNovo shall issue to Yissum such number of ordinary shares equal to a certain percentage of all TyrNovo shares.

TyrNovo is required to indemnify Yissum, the Hebrew University of Jerusalem, their directors, employees, executive officers, consultants or representatives and any other persons acting on their behalf under the license against any liability, including product liability, damages, losses, expenses, fees and reasonable legal expenses arising out of TyrNovo's actions or omissions or which derive from its use, development, manufacture, marketing, sale or sublicensing of any licensed product, licensed technology, and certain information obtained under the TyrNovo MTAs, or exercise of the Yissum License Agreement, and the TyrNovo MTAs.

TyrNovo has agreed to maintain, and to add Yissum as an additional insured party with respect to, clinical trials, comprehensive general liability and product liability insurance as well as an insurance policy with respect to the foregoing indemnification prior to the time when it commences clinical trials and concludes its first commercial sale.

The term of the Yissum License Agreement shall expire upon the later of (i) the date of expiration in such country of the last to expire licensed patent included in the licensed technology; or (ii) the end of a period of 15 year of the first commercial sale in such country, while the license granted under the Yissum License Agreement will terminate upon the later of (unless the license has been earlier terminated or expired) (i) the date of expiration in such country of the last to expire licensed patent included in the licensed technology; (ii) the date of expiration of any exclusivity on the product granted by a regulatory or government body in such country; or (iii) the end of a period of 15 year of the first commercial sale in such country.

TyrNovo has the right to terminate the Yissum License Agreement upon a prior written notice. Either party has the right to terminate the Yissum License Agreement if the other party is in material breach and has not cured such material breach within a certain number of days as of the receipt of a written notice notifying it of such breach. Additionally, Yissum has the right to terminate the Yissum License Agreement immediately in the event that TyrNovo does not comply with its obligation (following a certain amount of months cure period) to use commercially reasonable efforts to develop and commercialize the products; if an attachment is made over the majority of TyrNovo's assets or if execution proceedings are taken against TyrNovo and are not set aside within a certain amount of days; or if TyrNovo challenges in any forum the validity of one or more of the licensed patents. Upon termination of the Yissum License Agreement, TyrNovo shall assign to Yissum all the results obtained during the development of the product. If Yissum licenses to third parties such results, then TyrNovo shall be entitled to a percentage of the net proceeds actually received by Yissum from such third parties, up to an amount covering TyrNovo's expenses incurred during the development of such assigned results.

Pain and Hypertension Segment - Consensi

We own two U.S. patents and we expect to be pursuing additional international patent applications relating to Consensi. The following is a brief description of our patent and trademark-related intellectual property:

On August 9, 2016, the United States Patent and Trademark Office (USPTO) issued patent #9,408,837 covering Consensi. The term of the patent, entitled "Ameliorating Drug-Induced Elevations In Blood Pressure By Adjunctive Use Of Antihypertensive Drugs," extends to February 28, 2030. The patent includes claims covering methods of ameliorating celecoxib-induced elevation of blood pressure by administering celecoxib and amlodipine separately or in combination.

On May 30, 2017, the USPTO issued patent #9,662,315 covering an oral dosage composition which includes both celecoxib and amlodipine. This patent was a divisional of the '837 patent and its term will run until May 22, 2029.

On July 6, 2017, we filed a U.S. provisional application in partnership with Dexcel which is related to pharmaceutical formulations of celecoxib and amlodipine and methods of preparing the same. An international application based on the U.S. provisional application was filed on July 4, 2018 and a National Stage Application was filed in China. A U.S. nonprovisional application was filed on June 14, 2018 based on the U.S. provisional application and U.S. Patent 10, 350,171 was issued from this application on July 16, 2019. This patent covers methods of preparing a pharmaceutical composition comprising celecoxib and amlodipine. A first continuation application including claims covering a pharmaceutical composition comprising amlodipine and celecoxib was allowed by the USPTO and we believe will issue as a patent in the near future. A second continuation application including claims covering methods for treating pain and/or hypertension by administering a pharmaceutical composition comprising amlodipine and celecoxib was issued as a patent on February 23, 2021.

On June 2, 2020, the USPTO registered the trademark Consensi.

On August 4, 2020, Lupin notified Purple and Coeptis, our distribution partner for Consensi, that it had filed an abbreviated NDA with the FDA to market a generic version of Consensi. Lupin also sent both parties a Paragraph IV Notice Letter alleging that certain of our patents are invalid and/or not infringed by Lupin's proposed generic product. In September 2020, we filed a complaint in the United States District Court for the District of New Jersey against Lupin and claimed that Lupin's proposed generic product infringes certain of our patents and sought declaratory and injunctive relief. On January 12, 2021, the court issued an order providing a schedule for the briefs and other items to be submitted, and the discovery to be conducted, by the parties, which will take place over the course of 2021.

Market exclusivity

In the branded pharmaceutical industry, the majority of a branded drug's commercial value is usually realized during the period in which the product has market exclusivity. In the U.S. and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there can often be very substantial and rapid declines in the branded product's sales. The rate of this decline varies by country and by therapeutic category, and the number of generic competitor entrants to the market, among other factors; however, following patent expiration, branded products often continue to have market viability based upon the goodwill of the product name, which typically benefits from trademark protection.

A pharmaceutical brand product's market exclusivity is generally determined by two forms of intellectual property: patent rights held by the brand company and any regulatory forms of exclusivity to which the NDA-holder is entitled.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals. Patents provide the brand company with the right to exclude others from practicing an invention related to the medicine. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms and processes for (or intermediates useful in) the manufacture of products, and polymorphs. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

Market exclusivity is also sometimes influenced by regulatory exclusivity rights. Many developed countries provide certain non-patent incentives for the development of medicines. For example, the U.S., the European Union and Japan each provide for a minimum period of time after the approval of a new drug during which the regulatory agency may not rely upon the data of the original party who developed the drug to approve a competitor's generic copy. Regulatory exclusivity rights are also available in certain markets as incentives for research on new indications, on orphan drugs and on medicines useful in treating pediatric patients. Regulatory exclusivity rights are independent of any patent rights and can be particularly important when a drug lacks broad patent protection. Most regulatory forms of exclusivity, however, do not prevent a competitor from gaining regulatory approval prior to the expiration of regulatory data exclusivity on the basis of the competitor's own safety and efficacy data on its drug, even when that drug is identical to that marketed by the innovator.

It is not possible to predict the length of market exclusivity for any of our branded products with certainty because of the complex interaction between patent and regulatory forms of exclusivity, and inherent uncertainties concerning patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that we currently estimate or that the exclusivity will be limited to the estimate.

Government Regulations and Funding

Pharmaceutical companies are subject to extensive regulation by foreign, federal, state and local agencies, such as the FDA in the U.S., the Ministry of Health in Israel, or the various European regulatory authorities. The manufacture, distribution, marketing and sale of pharmaceutical products are subject to government regulation in the U.S. and various foreign countries. Additionally, in the U.S., we must follow the rules and regulations established by the FDA requiring the presentation of data indicating that our products are safe and efficacious and are manufactured in accordance with cGMP regulations. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, our products may be subject to detention and/or seizure, shipments of our products could be refused entry into the United States, and we may be criminally prosecuted. We and our manufacturers and clinical research organizations may also be subject to regulations under other foreign, federal, state and local laws, including, but not limited to, the U.S. Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries. As a result, pharmaceutical companies must ensure their compliance with the Foreign Corrupt Practices Act and federal healthcare fraud and abuse laws, including the False Claims Act.

These regulatory requirements impact our operations and differ from one country to another, so that securing the applicable regulatory approvals of one country does not necessarily imply the approval of another country. The approval procedures involve high costs and are manpower intensive, usually extend over many years and require highly skilled and professional resources.

U.S. Food and Drug Administration Approval Process

The steps usually required to be taken before a new drug may be marketed in the U.S. generally include:

- completion of pre-clinical laboratory and animal testing;
- completion of required chemistry, manufacturing and controls testing;
- the submission to the FDA of an IND application, which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- performance of (or reference to) adequate and well-controlled human clinical trials and studies to establish the safety, pharmacokinetics and efficacy of the proposed drug for its intended use;
- submission and approval of an NDA; and
- agreement with FDA of the language on the package insert.

Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND process.

In all the countries that are signatories of the Helsinki Declaration (including Israel), the prerequisite for conducting clinical trials (on human subjects) is securing the preliminary approval of the competent authorities of that country to conduct medical experiments on human subjects in compliance with the other principles established by the Helsinki Declaration.

The clinical testing of a drug product candidate generally is conducted in three sequential phases prior to approval, but the phases may overlap or be combined. A fourth, or post approval, phase may include additional clinical studies. The phases are generally as follows:

- *Phase I.* The Phase I clinical trial is generally conducted on 8-20 healthy volunteers. Phase I clinical trials typically involve administering escalating doses of the therapeutic candidate in the healthy volunteers to assess safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, and especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients;

- *Phase II.* The Phase II clinical trial involves administering the therapeutic candidate to a small population of sick patients to identify possible adverse events, or safety risks, and preliminary indicia of efficacy for the targeted disease or condition;

- *Phase III.* The Phase III clinical trial usually comprises multi-center, double-blind controlled trials in hundreds or even thousands of subjects at various sites to assess as fully as possible both the safety and the effectiveness of the drug. Specifically, the Phase III clinical trial is intended to make a comparison between the therapeutic candidate and the standard therapy and/or placebo. These trials are intended to establish the overall benefit/risk profile of the product and provide an adequate basis for product labeling; and

- *Phase IV*. In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase IV clinical trials.

Clinical trials must be conducted in accordance with the FDA's good clinical practices, or GCP, requirements. The FDA may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at study sites that the IRB oversees and also may halt a study, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical studies, mostly in certain types of Phase III clinical trial studies where it is required under the applicable clinical trial protocol, are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group recommends whether or not a trial may move forward at designated check points based on access to certain data from the study. The clinical study sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

As a therapeutic candidate matures through the clinical testing phases, manufacturing processes are further defined, refined, controlled, and eventually validated around the time that the Phase III clinical trial is completed. The level of control and validation required by the FDA increases as clinical studies progress. We and the third-party manufacturers on which we rely for the manufacture of our therapeutic candidates and their respective components (including the APIs) are subject to requirements that drugs be manufactured, packaged and labeled in conformity with cGMP. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping and other requirements.

Assuming completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of an NDA, requesting approval to market the product for one or more indications, together with payment of a user fee, unless waived. An NDA includes all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information on the chemistry, manufacture, controls and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA.

If an NDA submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act, or PDUFA, the FDA's goal is to complete its initial review and respond to the applicant within ten months of submission, unless the application relates to an unmet medical need, or is for a serious or life-threatening indication, in which case the goal may be within six months of NDA submission. However, PDUFA goal dates are not legal mandates and the FDA response often occurs several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the NDA. The NDA review process can, accordingly, be very lengthy. During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive and the FDA and/or any advisory committee it appoints may interpret data differently than the applicant.

After the FDA evaluates the NDA and performs a pre-approval inspection, or "PAI", on manufacturing facilities where the drug product and/or its API will be produced, the FDA will either approve commercial marketing of the therapeutic candidate with prescribing information for specific indications or issue a complete response letter indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA. If the complete response letter requires additional data and the applicant subsequently submits that data, the FDA nevertheless may ultimately decide that the NDA does not satisfy its criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing. Such post-marketing testing may include Phase IV clinical trials and surveillance to further assess and monitor the product's safety and efficacy after approval. Regulatory approval of drug product candidates for serious or life-threatening indications may require that participants in clinical studies be followed for long periods to determine the overall survival benefit of the drug product candidate.

If the FDA approves one of our therapeutic candidates, we will be required to comply with a number of post-approval regulatory requirements. We would be required to report, among other things, certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of our therapeutic candidates. Also, quality control and manufacturing procedures must conform to cGMP for approved drug products after our NDA is approved, if at all, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and recordkeeping requirements. If we seek to make certain changes to an approved product, such as certain manufacturing changes, we will need FDA review and approval before the change can be implemented. For example, if we change the manufacturer of a product or our API, the FDA may require stability or other data from the new manufacturer, and such data will take time and are costly to generate, and the delay associated with generating these data may cause interruptions in our ability to meet commercial demand, if any. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

Section 505(b)(2) New Drug Applications

With respect to applications for therapeutic candidates that comprise APIs of one or more previously approved drug products a drug sponsor may file a 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA: a 505(b)(1) NDA. Section 505(b)(2) of the Food, Drug, and Cosmetic Act, or FDC, was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Since the studies or clinical trials have already been successfully performed and reviewed by the FDA, the 505(b)(2) NDA can expedite the approval process. Generally, the application is typically used for drug approval to treat new indications of a previously approved drug or new formulations of previously-approved products. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs that have a new dosage form, strength, route of administration, formulation or indication.

The Hatch-Waxman Amendments permit the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's conclusions from prior review of such studies. The FDA may require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication supported by the Section 505(b)(2) application. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2).

To the extent that the Section 505(b)(2) applicant is relying on the FDA's conclusions regarding studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, or Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the reference product has expired. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized.

Section 505(b)(1) New Drug Applications

A Section 505(b)(1) NDA or BLA, known as the "full NDA or BLA," is an application that contains full reports of investigations of safety and efficacy performed by the drug sponsor. CM24 and NT219 are not a combination therapeutic candidate or a therapeutic candidate that is comprised of an API that has already undergone some or all necessary human clinical trials in another therapeutic candidate. Therefore, if CM24 or NT219 are approved for human clinical trials by the FDA or any foreign regulatory agency and shows adequate safety and efficacy data in human clinical trials, we anticipate that CM24 and NT219 will require a 505(b)(1) BLA or NDA.

Special Protocol Assessment

The special protocol assessment, or SPA, process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase III clinical trials that are intended to form the primary basis for determining a drug product's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial design and data analysis plans, within 45 days of receipt of the request.

The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the therapeutic candidate with respect to effectiveness of the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement, such as under the following circumstances:

- public health concerns emerge that were unrecognized at the time of the protocol assessment, or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;
- a sponsor fails to follow a protocol that was agreed upon with the FDA; or
- the relevant data, assumptions or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts.

In addition, a documented SPA may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study.

European Regulatory Authorities

In the event that we wish to perform trials in Europe or market or sell our Consensi therapeutic candidate in Europe, we must apply to an applicable country's regulatory authorities with a request to approve our therapeutic candidates according to the Mutual Recognition Procedure (MRP), which is a procedure applied by European Directive No. 2001/83/EC that enables access to medicinal products (drugs) in 27 countries of the European Union. The MRP approval process requires the applicant to receive approval in one of the EU countries and then apply for recognition of the other member countries to acknowledge the approval within their territory. While the Company engaged an external consultant to assist the Company in applying for regulatory approval of Consensi in Europe, EU regulatory authorities have indicated to us that because of the differences between EU regulations and FDA regulations regarding combination products, it would be more difficult to obtain marketing approval in the EU than in the U.S. We do not anticipate submitting a marketing application for Consensi to any EU countries in the immediate future. Other therapeutic candidates, such as NT219 or CM24, may be approved through either the MRP or through the Centralized Process in which a single application provides approval for all EU member states.

The Israeli Ministry of Health

Our operations are subject to permits from the Israeli Ministry of Health on three levels:

First, pertaining to the import of drugs and/or raw materials, we are required to apply to the Ministry of Health for approval from its medical accessories and devices unit (AMR).

Second, pertaining to research and development, when we conduct trials in human in Israel, the trials will be subject to the approval of the Helsinki Committee, which acts by force of the Public Health Regulations (Trials in Human Beings), 1980 (Trials in Human Subjects Regulations) and according to the guidelines of the Helsinki declaration, or any other approval required by the Ministry of Health. According to the Trials in Human Beings Regulations, the Helsinki Committee must plan and approve every experimental process that involves human beings. The Helsinki Committee is an institutional committee that acts in the medical institution in Israel where the trial is performed and is the party that approves and supervises the entire trial process. In practice, the physician, who is the chief researcher, submits an application trial protocol to the committee that includes, among other documents also the investigator brochure, clinical trial protocol and the informed consent form, on behalf of the requesting party. The committee forwards its decisions regarding the requests for medical trials that were approved by the committee to the manager of the medical institute and the manager has the authority to approve the requests without additional approval of the Ministry of Health. According to the procedure for medical trials in human beings of the Ministry of Health, the Helsinki Committee will not approve performance of a medical trial, unless it is absolutely convinced that the following conditions, among others, are fulfilled: (a) the expected benefits for the participant in the medical trial and to the requesting party justify the risk and the inconvenience involved in the medical trial to its participant; (b) the available medical and scientific information justifies the performance to the requested medical trial; (c) the medical trial is planned in a scientific manner that enables a solution to the tested question and is described in a clear, detailed and precise manner in the protocol of the medical trial, conforming with the Helsinki principles declaration; (d) the risk to the participant in the medical trial is as minimal as possible; (e) optimal monitoring and follow-up of the participant in the medical trial; (f) the initiator, the chief researcher and the medical institute are capable and undertake to allocate the resources required for adequate execution of the medical trial, including qualified personnel and required equipment; (g) the principal investigator, the secondary investigator have the appropriate training in the conduct of clinical trials and have necessary professional experience in conducting such said clinical trials; the investigators will follow GCP guidelines, the MOH and local SOPs; and (h) the nature of the commercial agreement with the chief researcher and the medical institute does not impair the adequate performance of the medical trial.

All phases of clinical studies conducted in Israel must be conducted in accordance with the Trials in Human Subjects Regulations, including amendments and addenda thereto, the Guidelines for Clinical Trials in Human Subjects issued by the Israel Ministry of Health (the Guidelines) and the International Conference for Harmonized Tripartite Guideline for Good Clinical Practice. The regulations and the Guidelines stipulate that a medical study on humans will only be approved after the Helsinki Committee at the hospital intending to perform the study has approved the medical study and notified the relevant hospital director in writing. In addition, certain clinical studies require the approval of the Ministry of Health. The Helsinki Committee will not approve the performance of the medical study unless it is satisfied that it has such potential advantages to the study participants and society at large that the risk and inconvenience for the participants and that the medical and scientific information justifies the performance of the requested medical study. The relevant hospital director, and the Ministry of Health, if applicable, also must be satisfied that the study is not contrary to the Helsinki Declaration or to other regulations. The Ministry of Health also licenses and regulates the marketing of pharmaceuticals in Israel, requiring the relevant pharmaceutical to meet internationally recognized cGMP standards.

Third, currently manufacturing of NY219 is conducted by service providers operating in Israel and, as such, these service providers are periodically audited by the Israel Ministry of Health in accordance with the laws and regulations pertaining to cGMP of investigational products.

Pervasive and continuing regulation in the U.S.

After a drug is approved for marketing and enters the marketplace, numerous regulatory requirements continue to apply. These include, but are not limited to:

- cGMP regulations require manufacturers, including third party manufacturers, to follow stringent requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product;

- labeling, promotion, and advertising regulations and the FDA prohibitions against the promotion of drugs for unapproved uses (known as off-label uses), as well as requirements to provide adequate information on both risks and benefits during promotion of the drug;

- approval of product modifications or use of a drug for an indication other than approved in an NDA and/or BLA;

- adverse drug experience regulations, which require us to report information on adverse events;

- post-market testing and surveillance requirements, including Phase IV trials, when necessary to protect the public health or to provide additional safety and effectiveness data for the drug;

- additional FDA reviews and approvals after the initial approval, particularly for any modification in conditions of use, active ingredient (s), route of administration, dosage form, strength or bioavailability, which may require a new 505(b)(2) submission accompanied by additional clinical data (which may require additional clinical studies) necessary to demonstrate the safety and effectiveness of the product with the proposed changes; and

- the FDA's recall authority, whereby it can ask, or under certain conditions order, drug manufacturers to recall from the market a product that is in violation of governing laws and regulation.

Other U.S. Healthcare Laws and Compliance Requirements

For products distributed in the United States, we are also subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct our business. Potentially applicable federal and state healthcare laws and regulations that may affect our business include the following:

- The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- The federal Anti-Inducement Law (also known as the Civil Monetary Penalties Law), which prohibits a person from offering or transferring remuneration to a Medicare or State healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program;

- The Ethics in Patient Referrals Act, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services (including outpatient prescription drugs) reimbursed under the Medicare program to entities with which the physicians or their immediate family members have a financial relationship, subject to narrow regulatory exceptions, and prohibits those entities from submitting claims to Medicare for payment of items or services provided to a referred beneficiary;

- The federal False Claims Act imposes criminal and civil penalties, as well as permitting civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

- The so-called federal "Sunshine Act" requires certain pharmaceutical and medical device companies to monitor and report certain financial relationships with physicians and other healthcare providers to CMS for disclosure to the public;

- The Health Insurance Portability and Accountability Act of 1996, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services. This statute also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on certain covered entities (including healthcare providers, health plans, and healthcare clearinghouses), and their business associates that provide services to or on behalf of the covered entity that involve the use or disclosure of individually identifiable health information; and

- Analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws that require pharmaceutical companies to report or disclose pricing or other financial information and to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

Reimbursement in the U.S.

Sales of our Consensi drug product and our oncology therapeutic candidates and other therapeutic candidates, if approved, in the United States may depend, in significant part, on the extent to which the approved products will be covered and reimbursed by third-party payers, such as government health programs, commercial insurance and managed health care organizations. Patients who are prescribed treatments for their conditions and providers prescribing treatments generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients and providers are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of therapies in which our products are used. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Decisions regarding the extent of coverage and amount of reimbursement to be provided for each of our product candidates will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our approved product and therapeutic candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The third-party payers are increasingly challenging the prices charged for medical products and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, discount and rebate requirements, and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payers do not consider our drug products to be cost-effective compared to other available therapies, they may not cover our Consensi drug product or therapeutic candidates, if approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drug products on a profitable basis.

The Medicare Prescription Drug Improvement and Modernization Act of 2003 (the MMA) imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries and included a major expansion of the prescription drug benefit under Medicare Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government reimbursement for some of the costs of prescription drugs may increase demand for our Consensi drug product or our therapeutic candidates, if approved, if they are covered by a Part D prescription drug plan. However, any negotiated prices for our Consensi drug product or our therapeutic candidates, if approved, covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers.

The Patient Protection and Affordable Care Act

In 2010, President Obama signed into law the Healthcare Reform Law, which resulted in sweeping changes across the U.S. health care industry. One of the primary goals of this comprehensive legislation was to extend health insurance coverage to currently uninsured legal U.S. residents through a combination of public program expansion and private sector health insurance reforms. To fund the expansion of insurance coverage, the Healthcare Reform Law contains measures designed to promote quality and cost efficiency in health care delivery and to generate budgetary savings in the Medicare and Medicaid programs, as well as enhance remedies for fraud and abuse enforcement. The Healthcare Reform Law's provisions are designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. Through modified reimbursement rates and other incentives, the U.S. government is requiring that providers identify the most cost-effective services, supplies and pharmaceuticals. This environment has caused changes in the purchasing habits of providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals. This attention may result in our Consensi drug product or our oncology therapeutic candidates, if approved, being chosen less frequently or the pricing being substantially lowered. Additionally, the Healthcare Reform Law includes provisions expanding and increasing pharmaceutical manufacturers' potential rebate and discount obligations for certain drugs covered under Medicare Part B and Medicaid programs. The Healthcare Reform Law also includes significant provisions that encourage state and federal law enforcement agencies to increase activities related to preventing, detecting and prosecuting those who commit fraud, waste and abuse in federal healthcare programs, including Medicare, Medicaid and Tricare. Since the enactment of the Healthcare Reform Law, numerous regulations have been issued providing further guidance on its requirements. Certain provisions have been subject to judicial and Congressional challenges and have been significantly modified by additional legislation. Substantial uncertainty remains as to the future of the Healthcare Reform Law as the U.S. Supreme Court is expected to issue an opinion in a case regarding whether and to what extent recent legislation affects the validity of the rest of the Healthcare Reform Law. There is no way to know whether, and to what extent, if any, the Healthcare Reform Law will remain in-effect in the future, and it is unclear how judicial decisions, subsequent appeals, additional legislative reform measures, or other efforts to repeal and replace or, possibly, to restore or expand the Healthcare Reform Law will impact the U.S. healthcare industry or our business.

*Grants from the Innovation Authority, or the IIA (formerly known as the Office of the Chief Scientist or the OCS)***.**

Under the Encouragement of Research, Development and Technological Innovation in the Industry Law, 1984, or the Innovation Law (formerly known as The Law for the Encouragement of Industrial Research and Development, 1984), and IIA's rules and guidelines, a qualifying research and development program is eligible for grants of up to 50% of the program's research and development expenses. In general, the recipient of the grants is required to return the grants by the payment of royalties on the revenues generated from the sale of products (and related services) developed (in whole or in part) according to, or as a result of, a research and development program funded by the IIA (at rates which are determined under the IIA's rules and guidelines, generally of 3% or 5% of revenues, which rates may be increased under certain circumstances) up to the aggregate amount of the total grants received by the IIA (which may be increased under certain circumstances, as described below), plus annual interest (as determined in the IIA's rules and guidelines). Following the full payment of such royalties and interest, there is generally no further liability for royalty payment. Nonetheless, the restrictions under the Innovation Law (as generally specified below) will continue to apply even after repayment of the full amount of royalties payable pursuant to the grants.

The pertinent obligations under the Innovation Law and the IIA's rules and guidelines are as follows:

- Local manufacturing obligation. The terms of the grants under the Innovation Law and the IIA's rules and guidelines require that a company which received IIA grants, or the Recipient Company, is prohibited from manufacturing products developed using these IIA grants outside of the State of Israel without receiving prior approval from the IIA (except for the transfer of less than 10% of the manufacturing capacity in the aggregate which requires only a notice). If the Recipient Company receives approval to manufacture products developed with IIA's grants outside of Israel, it will be required to pay increased royalties to the IIA, up to 300% of the grant amount plus accrued interest, depending on the manufacturing volume that is performed outside of Israel. The Recipient Company may also be subject to accelerated royalty repayment rates. A Recipient Company also has the option of declaring in its IIA grant application its intention to exercise a portion of the manufacturing capacity abroad, thus avoiding the need to obtain additional approval following the receipt of the grant and avoiding the need to pay increased royalties to the IIA.

- Certain reporting obligations. A recipient of IIA grant is required to notify the IIA of certain events enumerated in the IIA's rules and guidelines.

- Know-how transfer limitation. The IIA's rules and guidelines restrict the ability to transfer know-how funded by the IIA outside of Israel. Transfer of IIA funded know-how outside of Israel requires prior IIA approval and in certain circumstances is subject to payment of a redemption fee to the IIA calculated according to formulas provided under the IIA's rules and guidelines, up to 600% of the grants amount plus accrued interest. Upon payment of such fee, the know-how and the manufacturing rights of the products supported by such IIA funding cease to be subject to the Innovation Law and to the IIA's rules and guidelines.

Approval of the transfer of IIA funded know-how to another Israeli company may be granted only if the recipient assumes all of our responsibilities towards the IIA, including the restrictions on the transfer of know-how and manufacturing rights outside of Israel (although such transfer will not be subject to the payment of a redemption fee, such transfer will include an obligation to pay royalties to the IIA from the income of such sale transaction as part of the royalty payment obligation).

Approval to manufacture products outside of Israel or consent to the transfer of IIA funded know-how, if requested, might not be granted or may be granted on terms that are not acceptable to us. The scope of the support received, the royalties that we have already paid to the IIA, the amount of time that has elapsed between the date on which the know-how was transferred and the date on which the IIA grants were received and the sale price and the form of transaction will be taken into account in calculating the amount of the payment to the IIA in the event of a transfer of IIA funded know-how outside of Israel.

The government of Israel does not own intellectual property rights in technology developed with IIA funding and there is no restriction on the export of products manufactured using technology developed with IIA funding. However, the know-how is subject to transfer of know-how and manufacturing rights restrictions as described above. The IIA's approval is not required for the export of any products resulting from the IIA research or development grants. In addition, the IIA in 2017 published rules and guidelines for the granting of licenses to use know-how developed as a result of research financed by the IIA to foreign entities. According to such rules, we will be required to receive the IIA's prior approval for the grant of such use rights, and we will be required to pay the IIA certain amount in accordance with the formula stipulated under these rules and guidelines. In August 2018, the IIA updated the rules and established a new mechanism with respect to the grant of a license by a company (which is part of a multinational corporation) that received grants from the IIA to its group entities to use its funded know-how. Such license is subject to the IIA's prior approval and to the payment of 5% royalties from the income deriving from such license. Such mechanism includes certain restrictions which must be met in order to be able to enjoy such lower royalty payment.

These restrictions may impair our ability to enter into agreements to perform or outsource manufacturing outside of Israel, or otherwise transfer or sell TyrNovo's IIA funded know-how outside of Israel without the approval of the IIA. Furthermore, in the event that we undertake a transaction involving the transfer to a non-Israeli entity of TyrNovo know-how developed with IIA funding pursuant to a merger or similar transaction, the consideration available to TyrNovo's and/or our shareholders may be reduced by the amounts it is required to pay to the IIA. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with the requirements under the Innovation Law and the IIA's rules and guidelines may subject TyrNovo to financial sanctions, to mandatory repayment of grants received by it (together with interest and penalties) and may expose TyrNovo to criminal proceedings. In addition, the Government of Israel may, from time to time, audit sales of products which it claims incorporate technology funded via IIA programs and this may lead to additional royalties being payable on additional products, and may subject such products to the restrictions and obligations specified hereunder.

To date, TyrNovo's technology has received grants from the IIA in a total amount of approximately NIS 5.5 million (approximately $1.71 million). Up until the date of this Annual Report on Form 20-F, no royalties have been paid in respect to the grants received by the IIA. There is no guarantee that TyrNovo will receive any further grants from the IIA or that the grants will be in the scope received in the past.

C. Organizational Structure

Our corporate structure consists of Purple Biotech Ltd., incorporated under the laws of the State of Israel, our wholly-owned subsidiaries, FameWave and Kitov USA Inc. (currently inactive), and our majority owned subsidiary TyrNovo, of which we own approximately 98.47% of its shares.

D. Property, Plant and Equipment

All of our facilities are leased, and we do not own any real property. The principal executive offices for Purple Biotech, TyrNovo and FameWave are in a commercial office building located in the Science Park in Rehovot, Israel. Our current office space of approximately 625 square meters is subject to a 63.5-month lease, which commenced on September 15, 2020 and expires on December 31, 2025, and we have an option to extend such lease for an additional 60 months beyond the current term. Of our office space, 200 square meters are subleased to a third party for a period of 12 months with an option for such sublessor to extend the sublease for an additional 12-month period. We have no material tangible fixed assets apart from the property described above. We believe our facilities are adequate and suitable for our current needs.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Annual Report on Form 20-F. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 20-F, particularly those in "Item 3. Key Information – D. Risk Factors." See also "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage company developing first-in-class, effective, and durable therapies by overcoming tumor immune evasion and drug resistance. Our oncology pipeline includes NT219 and CM24. NT219 is a small molecule that simultaneously targets IRS1/2 and STAT3. In the second half of 2020 we commenced a phase 1/2 study of NT219 as a single agent followed by a dose escalation phase of NT219 as a single agent in patients with solid tumors, followed by a dose escalation phase of NT219 in combination with cetuximab for the treatment of recurrent and/or metastatic solid tumors and squamous cell carcinoma of the head and neck cancer or colorectal adenocarcinoma, and an expansion phase of NT219 at its recommended phase 2 level in combination with cetuximab in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck. CM24 is a humanized monoclonal antibody that blocks CEACAM1, an immune checkpoint that supports tumor immune evasion and survival through multiple pathways. We are advancing CM24 as a combination therapy with anti-PD-1 checkpoint inhibitors in selected cancer indications in a phase 1 study followed by a phase 2 for the treatment of non-small cell lung cancer and pancreatic cancer. We have entered into a clinical collaboration agreement, as amended, with Bristol Myers Squibb for the planned phase 1/2 clinical trials to evaluate the combination of CM24 with the PD-1 inhibitor nivolumab (Opdivo) in patients with non-small cell lung cancer and in combination with nivolumab in addition to nab-paclitaxel (ABRAXANE) in patients with pancreatic cancer.

CM24 is a humanized monoclonal antibody directed against CEACAM1, an immune checkpoint protein belonging to the Human CEA (Carcino-Embryonic Antigen) protein family. Evidence has shown that CEACAM1 is expressed on tumor infiltrating lymphocytes and is up-regulated in several cancer types. Moreover, CEACAM1 has been shown to be associated with angiogenesis as well as immune evasion of cancer from the immune system. CEACAM1 is associated with mechanisms of trophism and metastases in cancer, manifest through mechanisms such as neutrophil extracellular traps. In a monotherapy phase 1 study, CM24 demonstrated safety and a stable disease rate of approximately 33% among the evaluable patients was noted.

NT219 is a therapeutic candidate that targets cancer pathways IRS1/2 and STAT3 and has shown activity in preclinical studies as monotherapy as well in combination and would be developed as stand-alone and in combination with other cancer drugs or treatments. The NT219 technology has been tested in a number of PDX models where human cancer cells are taken and transplanted into mice and then used to test various cancer drugs. NT219 has been tested against and in combination with various classes of cancer drugs that have been recently developed as well as older standard chemotherapy.

We are also the owner of Consensi, a fixed-dose combination of celecoxib and amlodipine besylate, for the simultaneous treatment of osteoarthritis pain and hypertension which was approved by the FDA for marketing in the U.S in May 2018. The FDA approved our NDA for Consensi for patients suffering from hypertension and from osteoarthritis for whom treatment with amlodipine for hypertension and celecoxib for the treatment of osteoarthritis are appropriate. Consensi is based on the generic substances celecoxib and amlodipine besylate. Celecoxib is the active ingredient of a known and approved-for-use drug designed primarily to relieve pain caused by osteoarthritis. Celecoxib is the active ingredient in the branded drug Celebrex. This combination is designed to simultaneously relieve pain caused by osteoarthritis and treat hypertension, which is one of the side effects of using non-steroidal anti-inflammatory drugs, or NSAIDs, for treating pain caused by osteoarthritis. In May 2020, we launched the U.S. commercial sales of Consensi which is being sold in the U.S. by Burke Therapeutics, the marketing partner of our U.S. distributor, Coeptis. We have also entered into marketing and distribution agreements for the commercialization of Consensi in each of China and South Korea, which are dependent upon achieving regulatory clearance or approval for Consensi in each of those respective countries.

In addition, we consider the acquisition of oncology therapeutic candidates at various stages of development. We currently have no binding agreements or commitments to complete any transaction for the possible acquisition of new therapeutic candidates or approved drug products.

Our goal is to become a significant player in the development of innovative drugs with a clinical and commercial added value, focusing on the oncology space.

Key elements of our strategy are to:

- Focus on oncology therapeutic assets for treatment of unmet medical need and having a significant market opportunity;
- leverage our expertise in the clinical and regulatory processes in the United States, together with our research and development capabilities and network of professional advisors, to efficiently develop drug candidates in clinical stages of development and achieve marketing authorization;
- expand our line of therapeutic candidates through the acquisition or in-licensing of technologies, products and drugs focused in oncology space and intended to meet clinical needs
- cooperate with third parties to both develop and commercialize therapeutic candidates in order to share costs and leverage the expertise of others; and
- secure sufficient funds for the performance of acquisitions and development programs

History of Losses

Since commencement of our pharmaceutical research and development operations, we have generated significant losses mainly in connection with the research and development of our therapeutic candidates. Such research and development activities are expected to expand over time and will require further resources if we are to be successful. As a result, we expect to continue incurring operating losses, which may be substantial over the next several years, and will need to obtain additional funds to further develop our research and development programs. As of December 31, 2020, we had an accumulated deficit of approximately $77.5 million.

We plan to fund our future operations through commercialization and out-licensing of our therapeutic candidates and to raise additional capital in the future through either debt or equity financing.

Components of Statement of Operations

Revenues

We began to generate revenues in 2017 for upfront and milestones achieved under our commercialization agreements for Consensi in South Korea and China and beginning in 2019 also in the U.S. Our agreement with our commercialization partners includes additional regulatory and sales related milestone payments as well as future royalties on sales. We cannot predict the timing of meeting those milestones and receiving the related milestone payments and royalty payments, if any.

Effective as of January 1, 2018, we adopted the IFRS 15 *Revenue from Contracts with Customers* ("IFRS 15") which provided new guidance on revenue recognition.

Research and Development Expenses

Our research and development costs comprise of basic scientific research, pre-clinical studies, CMC development, clinical studies, post marketing commitments and medical research. Our research and development team combine clinical and regulatory development expertise mainly in the United States and Israel and the research and development capabilities of our scientists in Israel. During the years 2014 through 2019, we focused on the clinical development, CMC development and regulatory activities related to Consensi, and since 2017 we also expanded into research and development of NT219, including pre-clinical development, mechanism of action research, CMC development and clinical development. Beginning in 2020 with the closing of the acquisition of FameWave, we expanded our research and development activities to include CM24, including CMC, regulatory and clinical development. A significant portion of our research and development activities, including our preclinical and clinical studies, are performed through subcontractors such as clinical research organizations (CROs) and third-party manufacturers.

Our research and development expenses may fluctuate depending on the scope and timing of certain high-expense activities such as clinical trials. For example, from 2014 through the first half of 2018, we performed Phase III and Phase III/IV clinical trials in connection with Consensi that increased our research and development costs. From that time until the second half of 2020 we did not conduct any clinical trials. In the second half of 2020 we commenced a phase 1/2 study of NT219 and prepared for the initiation of our phase 1/2 study of CM24 primarily by manufacturing of CM24, which increased our research and development expenses in 2020, and we intend to initiate a phase 1/2 study of CM24 in late 2021, which will increase our research and developments expenses in 2021 and beyond.

Research and development expenses also include compensation for our employees and consultants for medical, regulatory and development work. As of December 31, 2020, our research and development staff consisted of six full-time employees, which we may expand as we expand our research and development activities including clinical trials.

We charge all research and development expenses to operations as they are incurred. We expect our research and development expense to remain our primary expense in the near future as we continue to develop our therapeutic candidates.

Set forth below is a summary of the research and development expenses for the years ended December 31, 2020, 2019 and 2018. Virtually all of the costs in such periods were incurred in connection with the development of Consensi, NT219 and CM24.

	Year Ended December 31,			
	2020	**2019**	**2018**	**Total**
	(U.S. dollars in thousands)			
Total research and development expenses	7,488	2,674	5,268	15,430

In addition to the major cost of pre-clinical studies, clinical trials, and CMC development, research and development expenses include consulting expenses for regulatory and project management work required for development of our therapeutic candidate portfolio. Set forth below is a summary of our research and development expenses based on the type of expenditure.

	Year Ended December 31,		
	2020	**2019**	**2018**
	(U.S. dollars in thousands)		
Payroll expenses and related expenses	1,209	1,012	933
Share-based payments	756	238	546
Sub-contractors	5,523	1,424	3,789
	7,488	2,674	5,268

Due to the inherently unpredictable nature of clinical development processes, we are unable to estimate with any certainty the costs we will incur in the continued development of our therapeutic candidates for potential commercialization. Our future research and development expenses will depend on the success of the preclinical and clinical trials for our product or therapeutic candidates, as well as availability of resources and based on ongoing assessments of the commercial potential of our products or therapeutic candidates and other drug candidates we may acquire. In addition, we cannot forecast with any degree of certainty which products or therapeutic candidates may be subject to future commercialization arrangements, when such commercialization arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. See “Item 3. Key Information – D. Risk Factors – If we and/or our potential commercialization partners are unable to obtain FDA and/or other foreign regulatory authority approval for our therapeutic candidates, we and/or our potential commercialization partners will be unable to commercialize our therapeutic candidates.”

As we obtain results from preclinical studies and/or clinical trials, we may elect to discontinue or delay development and preclinical studies and/or clinical trials for certain products or therapeutic candidates in order to focus our resources on more promising therapeutic candidates or projects. Alternatively, we may elect to expend more resources for our current products and therapeutic candidates than currently anticipated. Completion of preclinical studies and/or clinical trials by us or our licensees may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a therapeutic candidate. See "Item 3. Key Information – D. Risk Factors – Risks Related to Our Business and Regulatory Matters."

The lengthy process of completing CMC and/or preclinical studies and/or clinical trials and seeking regulatory approvals for four therapeutic candidates requires substantial expenditures. Any failure or delay in completing preclinical and/or clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of compensation for directors, employees and consultants in executive and operational functions. Other significant selling, general and administrative expenses include professional fees for outside accounting and legal services, travel costs, insurance premiums and legal expenses less reimbursement of legal expenses associated with class action claims.

Other Expenses (income)

Other income in 2018 represent the fair value of the rights granted to Taoz in 2017 as part of the Company's settlement with Taoz regarding the acquisition of TyrNovo. Such rights were subsequently canceled following the acquisition of the remaining shares held by Taoz during 2018.

Finance Income and Finance Expense

Finance expense comprises primarily changes in the fair value of financial liabilities as well as bank fees. Finance Income comprises changes in the fair value of financial liabilities and interest income from funds held in bank deposits.

Adjusted Operating loss

Adjusted operating loss is defined as operating loss, plus non-cash share-based compensation expenses. Our management believes that excluding non-cash charges related to share-based compensation provides useful information to investors because of its non-cash nature, varying available valuation methodologies among companies and the subjectivity of the assumptions and the variety of award types that a company can use under the relevant accounting guidance, which may obscure trends in our core operating performance. We present adjusted operating loss because we use this non-IFRS financial measures to assess our operational performance, for financial and operational decision-making, and as a means to evaluate period-to-period comparisons on a consistent basis. Management believes this non-IFRS financial measure is useful to investors because: (1) it allows for greater transparency with respect to key metrics used by management in its financial and operational decision-making; and (2) it excludes the impact of non-cash item that is not directly attributable to our core operating performance and that may obscure trends in the core operating performance of the business. Non-IFRS financial measures have limitations as an analytical tool and should not be considered in isolation from, or as a substitute for, our IFRS results. We expect to continue reporting non-IFRS financial measures, adjusting for the item described above, and we expect to continue to incur expenses similar to certain of the non-cash, non-IFRS adjustments described above. Accordingly, unless otherwise stated, the exclusion of this and other similar items in the presentation of non-IFRS financial measures should not be construed as an inference that these items are unusual, infrequent or non-recurring. Adjusted operating loss is not a recognized term under IFRS and do not purport to be an alternative to IFRS net operating loss as an indicator of operating performance or any other IFRS measure. Moreover, because not all companies use identical measures and calculations, the presentation of adjusted operating loss may not be comparable to other similarly titled measures of other companies.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with IFRS as issued by the IASB, requires companies to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates and judgments are subject to an inherent degree of uncertainty and actual results may differ. Our significant accounting policies are more fully described in Note 3 to our annual financial statements included elsewhere in this Annual Report on Form 20-F. Critical accounting estimates and judgments are evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances, and are particularly important to the portrayal of our financial position and results of operations.

Fair value measurement of non-trading derivatives

We had non-registered warrants that were classified as derivative liabilities. The fair value of such warrants was determined using the Black & Scholes valuation method. During 2019 and 2020, these warrants were registered and therefore they were reclassified from financial liabilities to equity in their fair value using the Black & Scholes valuation method. At the end of 2020 we no longer had such derivatives, since all such warrants were registered.

Assessment of Probability of Contingent Liabilities

The company makes assessments whether it is more likely than not that an outflow of economic resources will be required in respect of legal claims pending against the Company.

Accounting Treatment of FameWave Acquisition

The acquisition of FameWave was accounted for as an asset acquisition by us rather than as a business combination under IFRS 3, Business Combinations because substantially all of the fair value of the assets acquired were concentrated in a group of assets acquired by FameWave prior to or concurrent with the consummation of the transaction. Furthermore, the acquired assets did not have outputs or employees. The assets acquired by us under the Acquisition Agreement include a license, other associated intellectual property, documentation and records, and drug materials. In addition, no goodwill was recognized on the acquisition date. The acquisition closed on January 7, 2020.

A. Operating Results

Comparison of the Year Ended December 31, 2020 to the Year Ended December 31, 2019

Revenues

Revenues for the year ended December 31, 2020 were $1.0 million, unchanged compared to $1.0 million for the year ended December 31, 2019. The revenues for the years ended December 31, 2019 and 2020 consisted of the milestone payments related to the Consensi commercialization agreement with Coeptis. Our agreements with our commercialization partners include additional regulatory and sales related achievement milestones as well as future royalties on sales.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2020 were $7.5 million, an increase of $4.8 million, or 180%, compared to $2.7 million for the year ended December 31, 2019. The increase resulted primarily from expenses related to the NT219 clinical trials initiated in 2020 and the preparation for the anticipated initiation of the CM24 clinical trials, including manufacturing costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses, net of reimbursement from insurance for legal fees, for the year ended December 31, 2020 were $6.1 million, an increase of $0.6 million, or 11.7%, compared to $5.5 million for the year ended December 31, 2019.

Operating Loss

Our operating loss for the year ended December 31, 2020 amounted to $12.6 million, compared with an operating loss of $7.2 million for the year ended December 31, 2019, a 76% increase mainly due to the increase in research and development expenses.

Adjusted Operating Loss

On a non-IFRS basis adjusted operating loss for the year ended December 31, 2020, was $10.0 million, an increase of $4.1 million from $5.9 million for the year ended December 31, 2019, mainly due to the increase in research and development expenses.

Finance Expenses, net

Finance expenses, net for the year ended December 31, 2020 was $15.5 million in comparison to finance income of $1.5 million for the year ended December 31, 2019. The decrease was primarily due to a $17.1 million increase in expenses on account of warrants, mainly from a change in the fair value of derivatives. See Note 18 to the financial statements for the year ended December 31, 2020, included in this Annual Report on Form 20-F.

Loss for the Period

Our net loss for the year ended December 31, 2020 amounted to $28.1 million, compared to a net loss of $5.9 million for the year ended December 31, 2019, an increase of $22.2 million. The increase was due to a $17.1 million increase in expenses on account of warrants, mainly from a change in the fair value of derivatives, and an increase of $4.8 million in research and development expenses.

Comparison of the Year Ended December 31, 2019 to the Year Ended December 31, 2018

Revenues

Total revenues for each of 2019 and 2018 were $1.0 million. The revenues for the year ended December 31, 2019, consisted of the first milestone payment related to Consensi commercialization agreement with Coeptis. The 2018 revenue is for upfront fees and milestones achieved under our commercialization agreements for Consensi in China.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2019 were $2.7 million, a decrease of $2.6 million, or 49.3%, compared to $5.3 million for the year ended December 31, 2018. The decrease in research and development expenses resulted primarily from a decrease in costs related to the clinical development of Consensi following FDA approval of the drug in May 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses, net of reimbursement from insurance for legal fees, for the year ended December 31, 2019 were $5.5 million, an increase of $1.0 million, or 22.2%, compared to $4.5 million for the year ended December 31, 2018. The increase resulted primarily from a $0.9 million annual fee paid to the FDA relating to Consensi.

Other Expenses (income)

In 2019, we did not incur other expenses or other income. For the year ended December 31, 2018, we had income of $0.9 million as a result of the cancelation of certain rights granted to Taoz in 2017. This cancelation was done as part of our acquisition of Taoz's holdings in TyrNovo.

Operating Loss

Our operating loss for the year ended December 31, 2019 amounted to $7.2 million, compared with an operating loss of $7.8 million for the year ended December 31, 2018, a 7.8% decrease. The decrease in operating loss reflects the decrease in research and development as mentioned above during the year ended December 31, 2018, offset in part by an increase in selling, general and administrative expenses.

Adjusted Operating Loss

On a non-IFRS basis adjusted operating loss for the year ended December 31, 2019 was $5.9 million, a decrease of $1.2 million from $7.1 million for the year ended December 31, 2018. The decrease was due to the decrease in research and development expenses mentioned above and in various selling, general and administrative expenses, offset in part by a one-time increase in FDA fees and a one-time decrease in other income.

Finance Income (Expense), net

Finance income, net for the year ended December 31, 2019 was $1.5 million in comparison to finance expense, net of $2.3 million for the year ended December 31, 2018. The change was related primarily to income from adjustments to fair value of warrants accounted as a derivative liability, that resulted in 2019 in an income of $1.5 million, and in 2018 an income of $2.7 million. See Note 18 to the financial statements for the year ended December 31, 2020, included in this Annual Report on Form 20-F.

Loss for the Period

Our net loss for the year ended December 31, 2019 amounted to $5.9 million, compared to a net loss of $5.6 million for the year ended December 31, 2018, an increase of $0.3 million, which is a result of the increase in other expenses.

B. Liquidity and Capital Resources

Our oncology therapeutic candidates are in the research and development stage and therefore, we do not generate revenues from those candidates, and our FDA-approved drug Consensi has generated limited milestone revenues. Since commencement of our operations as a pharmaceutical research and development company, our activities have primarily been financed by equity offerings, as well as private loans which were subsequently fully repaid. We have raised gross proceeds of approximately NIS 52 million (approximately $9.2 million based on the representative rates of exchange on the dates of the closings, March 3, 2014, September 3, 2014, and March 30, 2015) from our public offerings on the TASE, approximately $13.0 million from our initial public offering on NASDAQ in November 2015, approximately $12.0 million for our follow-on public offering on NASDAQ in July 2016, approximately $3.5 million from a registered direct offering in July 2017, approximately $8.1 million from a registered direct offering in June 2018 and approximately $6.0 million from a registered direct offering in January 2019.

In January 2020, we raised $3.5 million in a private placement as part as part of the acquisition of FameWave.

On March 16, 2020, we consummated a public offering of an aggregate 962,000 ADSs and pre-funded Warrants to purchase 1,038,000 ADSs (exercisable at $0.001 per each ADS), and 2,000,000 investor warrants for gross proceeds of $6.0 million prior to deducting placement agent fees and other offering expenses. We will receive gross proceeds from the investor warrants solely to the extent such warrants are exercised for cash. The investor warrants are exercisable at an exercise price of $3.25 per ADS and will expire five years from March 16, 2020. In addition, we issued to the placement agent warrants to purchase 140,000 ADSs. The placement agent warrants are exercisable immediately for a term of five years at an exercise price of $3.75 per ADS.

On April 20, 2020, we consummated a warrant exercise transaction, pursuant to which certain holders of existing warrants to purchase 2.0 million ADSs exercised such warrants at an exercise price of $3.25 per share, for aggregate proceeds of approximately $6.5 million, prior to deducting placement agent fees and estimated offering expenses. In consideration for the immediate exercise of the warrants, we issued in a private placement to the exercising holders unregistered warrants to purchase up to an additional aggregate 2.2 million ADSs. The warrants are immediately exercisable for a term of exercise to five and one-half years at an exercise price of $3.25.

On May 8, 2020, we consummated a registered direct offering of 2,500,000.2 ADSs at a purchase price of $4.00 per ADS for aggregate gross proceeds of approximately $10.0 million prior to deducting placement agent fees and other offering expenses. We also issued to the investors unregistered warrants to purchase up to an aggregate of 2,500,000.2 ADSs. The warrants have a term of 5.5 years, are exercisable immediately and have an exercise price of $4.00 per ADS. In addition, we issued to the placement agent warrants to purchase 175,000 ADSs. The placement agent warrants are exercisable immediately for a term of five years at an exercise price of $5.00 per ADS.

On June 25, 2020, we consummated a registered direct offering of 3,888,889.2 ADSs and warrants to purchase up to an aggregate of 1,944,444.6 ADSs, at a combined purchase price of $9.00 per ADS for aggregate gross proceeds of approximately $35.0 million prior to deducting placement agent fees and other offering expenses. The warrants have a term of five years, are exercisable immediately and have an exercise price of $9.00 per ADS. In addition, we issued to the placement agent warrants to purchase 194,444.5 ADSs. The placement agent warrants are exercisable immediately for a term of five years at an exercise price of $11.25 per ADS.

As of December 31, 2020, we had on hand approximately $60.8 million in cash and cash equivalents and in short- and long-term deposits. We believe that our current cash and cash equivalents are sufficient to satisfy liquidity requirements for the next 12 months. Since we do not know whether we will generate significant revenues from our drugs and therapeutic candidate, if ever, should we decide to continue the development of CM24 and NT219 and to develop any additional therapeutic candidates, we may need substantial additional funds to acquire, develop, and/or commercialize such therapeutic candidates. However, additional financing may not be available on acceptable terms, if at all. Our long-term capital requirements will depend on many factors, including:

- the regulatory path of our therapeutic candidates;
- our ability to successfully commercialize Consensi and our CM24 and NT219 therapeutic candidates, including securing commercialization agreements with third parties and favorable pricing and market share as well as the success of our distributors' marketing and sales efforts;
- the progress, success and cost of our preclinical studies and/or clinical trials and research and development programs;
- the costs, timing and outcome of regulatory review and obtaining regulatory approval of our therapeutic candidates and addressing regulatory and other issues that may arise post-approval;
- the costs of obtaining and enforcing our issued patents and defending intellectual property-related claims; and
- our consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated.

If we are unable to successfully commercialize or out-license Consensi or our therapeutic candidates or obtain future financing, we may be forced to delay, reduce the scope of, or eliminate one or more of our research and development programs related to the therapeutic candidate, which may have a material adverse effect on our business, financial condition and results of operations.

Cash Flow

Operating activities

For the year ended December 31, 2020, net cash flow used in operating activities was approximately $12.1 million compared to approximately $5.6 million and $8.5 million for the years ended December 31, 2019 and 2018, respectively. The increase of $6.5 million in net cash flow used in operating activities in 2020 compared to 2019 was mainly due to an increase in finance expenses offset by a decrease in net change in assets and liabilities. The decrease of $2.9 million in net cash flow used in operating activities in 2019 compared to 2018 was due to a decrease in operating losses, net of adjustments, offset by a decrease in net change in assets and liabilities. The cash used in operating activities consisted of expenses associated with expenses related to the development and manufacturing of Consensi, expenses for the development of NT219 and CM24 and general and administrative expenses, net of revenues from the Consensi commercialization agreement with Coeptis.

Investment activities

We had no significant investment activities during the years ended December 31, 2018. In the year ended December 31, 2019, our investment activities consisted of investment in financial assets. In the year ended December 31, 2020, our investment activities consisted of investment in cash deposits.

Financing activities

For the year ended December 31, 2020, financing activities consisted of $3.5 million net proceeds received from the January 2020 private placement as part as part of the FameWave acquisition, $4.6 million net proceeds from the March 2020 public offering in the United States, $7.1 million net proceeds from the April 2020 warrant exercise transaction, $8.4 million net proceeds from the May 2020 registered direct offering and $31.0 million net proceeds from the June 2020 registered direct offering. For the year ended December 31, 2019, financing activities consisted of $5.1 million net proceeds received from the January 2019 issuance of ADSs in a registered direct offering and unlisted, unregistered warrants in a concurrent private placement. For the year ended December 31, 2018, financing activities consisted of the $7.4 million net proceeds received from the June 2018 issuance of ADSs in a registered direct offering and unlisted, unregistered warrants in a concurrent private placement. The net proceeds from the financing activities in 2020, 2019 and 2018 were used to finance the operating activities of the Company.

As of December 31, 2020, we had no borrowings.

As of December 31, 2020, and as of the date of this Annual Report on Form 20-F, we had no commitments for capital expenditures.

C. Research and Development, Patents and Licenses

See above under Item 5 - Operating and Financial Review and Prospects – A. Operating results – Components of Statement of Operations - Research and Development Expenses."

D. *Trend Information*

We are a pharmaceutical company which focuses its activities on the development of our therapeutic candidate and commercialization of our FDA approved drugs. It is not possible for us to predict with any degree of accuracy the outcome of our research and development or commercialization efforts with regard to our therapeutic candidate. Our research and development expenditure is our primary expenditure, although we may incur substantial expenditures should we acquire any new therapeutic candidates. Increases or decreases in research and development expenditure are primarily attributable to the level and results of our CMC, preclinical studies and clinical trial activities and the amount of expenditure on those studies and trials.

E. Off-Balance Sheet Arrangements

We are not party to any material transactions, agreements or other contractual arrangements with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our significant contractual obligations as of December 31, 2020.

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
		(U.S. dollars in thousands) (unaudited)			
Operating Lease Obligations (1)	1,087	222	445	420	-
Purchase Obligations (2)	2,857	2,652	-	205	-
Other Long-term Liabilities (3)	265	-	-	265	-
Total	4,209	2,874	445	890	-

(1) Reflects our office lease and car lease obligations.
(2) Reflects obligations to research and development service providers in connection with the development of NT219 and orders for manufacturing of Consensi.
(3) Includes post-employment benefit liabilities.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth the name, age and position of each of our executive officers and directors, as of the date of this Annual Report on Form 20-F. The inclusion of any individual in this table does not necessarily imply that such individual is an officer or office holder as such terms are defined under applicable law.

Name	Age	Position
Eric Rowinsky, M.D.[(1)]	64	Independent Director and Chairman of the Board of Directors
Isaac Israel	42	Chief Executive Officer and Director
Simcha Rock, CPA, MBA[(1)]	70	Director
Steven Steinberg[(2)(3)]	59	Independent Director
Ido Agmon, MBA[(1)(2)(3)]	43	Independent Director
Robert Gagnon	46	Independent Director
Revital Stern-Raff, CPA, MBA[(2)]	46	Independent Director
Gil Efron, CPA, MA	55	Deputy Chief Executive Officer and Chief Financial Officer
Hadas Reuveni, Ph.D.	53	Vice President or Research and Development
Michael Schickler, Ph.D.	63	Head of Clinical Operations
Bertrand Liang	58	Chief Medical Officer
Ido Morpurgo	48	Vice President of Operations

(1) Member of Nominations Committee
(2) Member of Audit Committee
(3) Member of Compensation Committee

Eric Rowinsky, M.D. has been Chairman of Purple Biotech's Board since October 2019. Dr. Eric Rowinsky's principal expertise is in the development and registration of novel therapeutics to treat cancer. Since November 2015, Dr. Rowinsky has served as Executive Chairman of the Board of Directors and President of Rgenix, Inc. Dr. Rowinsky also serves as the Chief Scientific Officer of Clearpath Development Inc., and has served as a consulting Chief Medical Officer of Oncotartis, Inc. since 2018 and Everest Medicines, Inc. since 2017. Additionally, Dr. Rowinsky has been an independent consultant since 2016 and works with many other life science companies in providing expertise in developing and registering a wide range of novel cancer therapeutics. Dr. Rowinsky served as Executive Vice President, Chief Medical Officer and Head of Research and Development of Stemline Therapeutics, Inc., a clinical-stage biopharmaceutical company, from November 2011 until October 2015. Prior to joining Stemline, Dr. Rowinsky was co-founder and Chief Executive Officer of Primrose Therapeutics, Inc., a start-up biotechnology company, from June 2010 until its acquisition in September 2011. He also served as a drug development and regulatory strategy consultant to the ImClone-Lilly Oncology Business Unit and several other biopharmaceutical and life sciences companies from 2010 to 2011. From 2005 to 2009, Dr. Rowinsky was Executive Vice President and Chief Medical Officer of ImClone Systems Inc., where he led the FDA approval of Erbitux for head and neck and colorectal cancers and advanced eight other monoclonal antibodies through clinical development. From 1996 to 2004, Dr. Rowinsky held several positions at the Cancer Therapy and Research Center, including Director of the Institute of Drug Development, or IDD, and the SBC Endowed Chair for Early Drug Development at the IDD. From 1996 to 2006, he was a Clinical Professor of Medicine at the University of Texas Health Science Center at San Antonio. From 1988 to 1996, Dr. Rowinsky was an Associate Professor of Oncology at The Johns Hopkins University School of Medicine. He was a longstanding National Cancer Institute principal and co-principal investigator from 1990 to 2004, and was integrally involved in pivotal clinical and preclinical investigations that led to the development of numerous cancer therapeutics, including paclitaxel, docetaxel, topotecan, irinotecan, erlotinib, gefitinib and temsirolimus among others. Dr. Rowinsky was also an Adjunct Professor of Medicine at New York University School of Medicine (2008-2018). Dr. Rowinsky presently serves on the boards of directors of the public companies Biogen Idec, Inc., Fortress Biosciences, Inc., and Verastem Inc. Dr. Rowinsky formerly served on the boards of directors of the public companies Navidea Biopharmaceuticals Inc. (2010-2018), BIND Therapeutics (2014-2016), and Biophytis S.A. (2018-2019), as well as at a number of privately held companies. Dr. Rowinsky received a B.A. degree from New York University (1977) and an M.D. degree from Vanderbilt University School of Medicine (1981). Dr. Rowinsky completed his residency in internal medicine at the University of California, San Diego (1984) and completed his fellowship in medical oncology at The Johns Hopkins Oncology Center (1987).

Isaac Israel has served as our chief executive officer and a member of Purple Biotech's Board since October 2012. Mr. Israel was the founding chief executive officer of BeeContact Ltd. (formerly TASE:BCNT), from 2001 until 2007. Since 2008, Mr. Israel has served as founding chief executive officer of Uneri Capital Ltd., a consulting firm in the capital markets field, owned by Mr. Israel, which specializes in the healthcare sector. Mr. Israel served as a member of the board of directors of various private and public healthcare corporations, including as chairman of the board of a public healthcare corporation, NextGen Biomed Ltd., which is traded on the TASE.

Simcha Rock, CPA, MBA, has served a member of Purple Biotech's Board since July 2013. Mr. Rock also serves as a strategic consultant to us. Mr. Rock served as our Chief Financial Officer from July 2013 until he retired from such position as of December 31, 2018. Prior to joining us, Mr. Rock was a private equity manager at Edmond de Rothschild Private Equity Management, a firm specializing in the management of venture capital and other private equity investments funds, from February 2000 until January 2011, with responsibility for all financial, legal and administrative matters for several investment funds. Prior to 2000, Mr. Rock held financial management positions at Intel Electronics Ltd., The Jerusalem College of Technology, and JC Technologies Ltd. Mr. Rock holds a B.A. degree from Yeshiva University and an MBA degree from Cleveland State University.

Steven Steinberg has served as a member of Purple Biotech's Board since July 2016. Since April 2017, Mr. Steinberg has been an independent financial consultant. From January 2015 through March 2017, Mr. Steinberg served as the chief financial officer of Glide Talk Ltd., a technology company in the video messaging and wearable technology arenas. From September 2013 to October 2014, Mr. Steinberg served as vice president, finance at Client Connect Ltd., a subsidiary of Conduit Ltd., and subsequent to an acquisition, of Perion Network, Ltd. a NASADQ listed company. Between August 2011 and August 2013, Mr. Steinberg acted as an independent financial consultant. From December 2002 until July 2011, Mr. Steinberg was employed by Answers Corporation, a NASDAQ listed company, where he served as chief financial officer. Prior to 2002, Mr. Steinberg held a number of finance and chief financial officer roles, following a ten-year period of service as an audit manager at Coopers & Lybrand (currently Price Waterhouse Coopers) in New York City. Mr. Steinberg holds a Bachelor of Business Administration degree from Florida International University – School of Business Administration, and was certified as a certified public account in New York State.

Ido Agmon, MBA, has served as a member of Purple Biotech's Board since June 2016. Since 2012, Mr. Agmon has been acting as an independent consultant and investment manager, providing start-ups, investment funds and technology-based ventures with advice in strategic& financial planning, fund-raising and related business development activities. Mr. Agmon serves as a member of the board of directors of an Israeli privately held start-up corporation. From 2014 until the end of 2016, Mr. Agmon was a manager of Aviv New-Tech (formerly Aviv Bio-Invest), a private investment fund which manages a portfolio of public Israeli & global biomed and technology companies, of which he was a co-founder, and where he was responsible for analysis and evaluation of investments in Israeli and global biomed companies. From 2009 until 2011, Mr. Agmon served as the CEO of Meytav Technology Incubator, an Israeli-based accelerator for biotech, pharma & medtech ventures with over 20 portfolio companies. Mr. Agmon has served as a board member at several biomed ventures. From 2007 until 2009, Mr. Agmon served as the Director of Business Development at ATI incubator, a technology incubator specializing in biomed and cleantech projects, responsible for deal-flow and project evaluation. Mr. Agmon holds a Bachelor's degree in Business Administration & Life Sciences from Tel Aviv University, Tel Aviv, Israel, and an MBA degree from the Hebrew University of Jerusalem, Israel.

Robert Gagnon, *MBA*, currently serves as Chief Business and Financial Officer of Verastem Oncology, a biopharmaceutical company committed to advancing new medicines for patients battling cancer. Before joining Verastem in 2018, Mr. Gagnon served as the Chief Financial Officer at Harvard Bioscience, Inc. Prior to this, Mr. Gagnon served as Executive Vice President, Chief Financial Officer and Treasurer at Clean Harbors, Inc., as well as Chief Accounting Officer and Controller at Biogen Idec, Inc. Earlier in his career, Mr. Gagnon worked in a variety of senior positions at Deloitte & Touche, LLP, and Price Waterhouse Coopers, LLP. Mr. Gagnon holds an M.B.A. degree from the MIT Sloan School of Management and a Bachelor of Arts degree in accounting from Bentley College.

Revital Stern-Raff, CPA, MBA has served as a member of Purple Biotech's Board since March 2017. Since August 2017, Ms. Stern-Raff has been an independent financial and accounting consultant. Between 2013 and August 2017, Ms. Stern-Raff served as the Chief Financial Officer of several municipal development and community association units of the City of Giv'atayim, Israel. Between 2006 and 2013, Ms. Stern-Raff held comptroller and economist positions at Ilex Medical Ltd., a publicly-traded medical diagnostic equipment company (TASE:ILX). Prior to 2006, Ms. Stern-Raff held several comptroller and public accounting positions. Between 2009 and 2012, Ms. Stern-Raff was an independent director at Real Imaging Holdings Ltd., a publicly traded breast cancer diagnostics company (TASE:RIMG). Ms. Stern-Raff is a licensed CPA in Israel, and holds an M.B.A. degree (Finance) and B.A. degree (Business Administration – Information Technology and Finance) from the Rishon Letzion College of Management in Israel.

Gil Efron has served as our Deputy Chief Executive Officer and Chief Financial Officer since October 2018. Prior to joining us, Mr. Efron served as Deputy CEO and CFO of Kamada Ltd., a NASDAQ and TASE dual-listed plasma-derived protein therapeutics company, from September 2011 to November 2017. Prior to that, Mr. Efron served as the CFO of NASDAQ listed RRsat Global Communications Ltd. (Nasdaq: RRST) from September 2005 to March 2011. Prior to that, Mr. Efron served in various finance executive positions. Mr. Efron holds a B.A. degree in Economics and Accounting and an M.A. degree in Business Administration from the Hebrew University of Jerusalem and was granted a certified public accountant's license in Israel.

Dr. Hadas Reuveni, Ph.D. has served as the Company's Vice President Research and Development since 2017. Dr. Reuveni a co-inventor of the TyrNovo technology, received her Ph.D., Summa Cum Laude, for anti-cancer drug discovery from the Hebrew University of Jerusalem. Dr. Reuveni has been involved in the scientific projects in TyrNovo's portfolio since 2005 and has nearly two decades of research and development experience in biotechnology. Dr. Reuveni founded NovoTyr Ltd. a biotech start-up company, a predecessor company to TyrNovo, developing small molecules for the treatment of cancer and neurodegenerative diseases, and between 2005 and 2012 she served as its CEO. Dr. Reuveni also founded and served as a director and chief science officer of AngioB Ltd., a start-up company that developed GPCR-based agents for multiple indications (2006-2010). Prior to these roles, Dr. Reuveni was the director of research & development at Keryx Biopharmaceuticals (NASDAQ:KRX) between 2001-2004. Dr. Reuveni has served as a scientific consultant for Integra Holdings Ltd., Campus Bio Management Ltd. and BioLineRX (NASDAQ/TASE BLRX). Dr. Reuveni holds a B.Sc. degree in chemistry, an M.Sc. degree in biological chemistry and a Ph.D. in biological chemistry and drug discovery, all from the Hebrew University of Jerusalem, Israel.

Michael Schickler, Ph.D., has served as the Company's Head of Clinical Operations since January 2020. Prior to assuming this role, Dr. Schickler served as the Chief Executive Officer of FameWave until the closing of the FameWave Acquisition. Dr. Schickler has also provided consulting services for medical device and healthcare companies since July 2018, advising on various matters pertaining to biopharmaceutical drug development, including as a consultant to the Company since March 2019. From May 2001 to July 2018, Dr. Schickler served as Chief Executive Officer of CureTech Ltd. ("CureTech"), a biotechnology company developing novel immunotherapies for the treatment and control of cancer. During his time at CureTech, Dr. Schickler led the company from the establishment of its operations through its development into a clinical-stage company with activities spanning basic research through GMP manufacturing and worldwide clinical operations. Dr. Schickler has served on the board of directors of CureTech since October 2018 and previously served on the board of directors of Accellta Ltd. Dr. Schickler received his Diploma in Business Administration from the University of Lincoln, Lincoln, United Kingdom, his Ph.D. in Biology from The Weizmann Institute of Science, Rehovot, Israel and his B.Sc. degree in Biology from The Faculty of Life Sciences, Tel Aviv University, Israel.

Bertrand Liang, M.D., Ph.D., and MBA has served as the Company's Chief Medical Officer since January 2020. Dr. Liang previously founded several biotechnology companies, including Tracon Pharmaceuticals, Coronado Biosciences (subsequently merged with Fortress Biotech) and Pfenex Inc. Earlier in his career, Dr. Liang was Site Head at Biogen Idec (now Biogen), leading pre-clinical and clinical development, and Vice President, New Ventures; managing member, Forward Medical Sciences (a venture capital firm). Dr. Liang also served as Vice President and Head of Hematology and Oncology at IDEC; and Global Development Leader at Amgen, where he led the development of various cytokines that received U.S. Food and Drug Administration approval, including Neulasta. Dr. Liang has also held academic positions at the National Cancer Institute, University of Colorado and University of Vermont, where he headed Human Medical Genetics. Dr. Liang is an alumnus of the Feinberg School of Medicine at Northwestern University, the Institute of Materials Research and Innovation, University of Bolton, the Law School at University of London, Boston University, Regis University, and the MIT Sloan School of Management. Dr. Liang has authored over 75 peer-reviewed publications, chapters and books, and edited a number of volumes in the fields of Neurology and Oncology.

Ido Morpurgo has served as the Company's Vice President Operations since August 2020. Most recently Mr. Morpurgo served as a Vice President Global Operations at Laline Israel from August 2019 until August 2020, and prior to that as Procurement Director at Kamada Ltd. from May 2015 until July 2019. Mr. Morpurgo holds a Bachelor of Science degree in Economics from the Hebrew University of Jerusalem, Israel, and an LLM degree from Bar Ilan University.

B. Compensation

The aggregate compensation paid, and benefits in-kind granted to or accrued on behalf of all our directors and officers for their services, in all capacities, to us during the year ended December 31, 2020, was approximately $3.6 million. As of December 31, 2020, the total amount set aside as an actuarial estimate by us to provide pension, retirement or similar benefits for our officers (we do not provide any such benefits to our directors in such capacities) was in the aggregate amount of approximately $265,000.

Our directors and executive officers hold exemption and indemnification letters and are covered under our D&O insurance policy. For information on exemption and indemnification letters granted to our officers and directors, see "Item 6.C. Board Practices - Exculpation, Insurance and Indemnification of Directors and Officers".

As of December 31, 2020, (i) options to purchase 6,053,023 of our ordinary shares granted to our officers and directors were outstanding, of which options to purchase 1,593,979 of our ordinary shares have vested; and (ii) 3,037,500 restricted stock units ("RSUs") awarded to our officers and directors were outstanding. For information on our 2016 Equity-Based Incentive Plan, see "Item 6. Directors, Senior Management and Employees—E. Share Ownership—2016 Equity-Based Incentive Plan." For information on the corporate approvals for officer and director compensation, see "Item 6.C – Board Practices – "Compensation of Directors and Executive Officers."

Director Compensation

We currently pay Purple Biotech's independent and non-executive non-chairman directors an annual fee of $40,000 for services as a member of our Board of Directors, an additional $3,500 annual fee for service on each permanent Board committee, and an additional $7,000 annual fee for service on the Board of Directors of a subsidiary (if applicable); provided, however, that the maximum annual fee for services on our Board of Directors, on Board committees and/or on the Boards of any subsidiaries shall not exceed $47,000. The above dollar denominated fees, and all other dollar denominated payments that we pay our directors based in Israel are paid in NIS based on the NIS/$ exchange rate at the beginning of the month in which such amounts are paid, but not lower than the exchange rate in effect on January 1, 2017. We pay Dr. Rowinsky, the chairman of our Board of Directors, an annual fee of $60,000 for services as a member of our Board of Directors, as Chairman of the Board, for service on any committee of the Board of Directors, and for service on the Board of Directors of a subsidiary. All such director annual fees shall be paid pro-rata for any service during part of a year.

Each of our Compensation Committee, Board of Directors and shareholders have also approved ancillary benefits such that we may subsidize ongoing corporate governance or other professional training for directors in amounts up to $5,000 per director per annum. We also reimburse the directors for any direct expenses incurred during the performance of their duties (e.g., travel, parking, telephone, meals, etc.).

At an extraordinary general meeting held on August 6, 2020, our shareholders approved, following the approval of our Compensation Committee and Board of Directors, the grant to each of our directors the following equity-based awards under our Equity-Based Incentive Plan: (i) to Isaac Israel, our Chief Executive Officer and a director, consisting of options to purchase up to 675,000 ordinary shares and 675,000 RSUs; (ii) to Dr. Eric Rowinsky, the Chairman of our Board of Directors, consisting of options to purchase up to 225,000 ordinary shares and 225,000 RSUs; and (iii) to each of our then serving directors, options to purchase up to 112,500 ordinary shares and 112,500 RSUs. Each of the equity awards vest over a period of three years from the date of grant, with one-third of each of the options and RSUs vesting on the first anniversary of the date of grant and the remaining options and RSUs vesting ratably on a quarterly basis during the two years thereafter. The options have an exercise price equal to $4.21 (which was equal to the average closing price of our (pre-reverse ratio change of) ADSs on the Nasdaq Capital Market during the 30 days prior to and including the date of the approval of the award by our Board of Directors). The equity awards were granted under our 2016 Equity-Based Incentive Plan, and in accordance with the terms of the plan the foregoing awards are subject to acceleration upon certain change of control events as set forth in the applicable award agreements.

There are no arrangements or understandings between us and any of our subsidiaries, on the one hand, and any of our directors, on the other hand, providing for benefits upon termination of their employment or service as directors of our company or any of our subsidiaries.

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.

Executive Compensation

The table below sets forth the annual compensation paid to each of our five most highly compensated office holders (as defined in the Companies Law) for the year ended December 31, 2020, broken out by component and on an individual basis, as recorded in our financial statements for such year. For so long as we qualify as a foreign private issuer, we are not required to comply with the proxy rules applicable to U.S. domestic companies to disclose the compensation of our chief executive officer and other two most highly compensated executive officers on an individual, rather than an aggregate, basis, rather we are required under Israeli law to disclose in the proxy statement for our annual general meeting of our shareholders (or to include a reference therein to other previously furnished public disclosure) the annual compensation of our five most highly compensated office holders on an individual basis, rather than on an aggregate basis, as recorded in the Company's financial statements for such year.

Name	Position	Salary or other payments[1]	Bonus payments or accruals	Share-based payment[2]	Total[3]
Isaac Israel	Chief Executive Officer and Director	375,318	134,778	618,649	1,128,745
Gil Efron	Chief Financial Officer and Deputy CEO	265,844	114,471	378,095	758,410
Dr. Bertrand Liang	Chief Medical Officer	345,368	101,519	306,708	753,595
Dr. Hadas Reuveni	Vice President of Research and Development	219,754	52,258	234,784	506,796
Dr. Michael Schickler	Head of Clinical Operations	158,375	60,762	149,544	368,681

1 Includes social benefits, such as payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds; vacation pay; and recuperation pay as mandated by Israeli law, and car lease or vehicle use reimbursement related benefits.

2 The fair value of share options granted to employees, directors and service providers was estimated using the fair value of our traded warrants with similar terms, making some adjustments to reflect the specific terms of the options based on the expected duration.

3 The total compensation amounts do not include any amounts recorded for an increase in actuarial estimate calculations for post-employment benefit liabilities for the office holder, nor any accruals for unused vacation time. Compensation amounts which were paid or otherwise measured in NIS have been translated into US$ for purposes of this report at average representative exchange rates for the year.

Agreements with Executive Officers

We have entered into engagement agreements with each of our executive officers. All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable laws.

Agreement with Mr. Isaac Israel

In September 2014, we entered into an employment agreement with Mr. Isaac Israel as our chief executive officer for the provision of services on an 80% basis. Effective as of May 1, 2016, Mr. Israel increased the scope of his engagement with the Company to 100%. As of May 1, 2016, Mr. Israel is engaged via a services agreement with Uneri Capital Ltd., a private company wholly owned by Mr. Israel, provided, however, that there is no difference to our costs and expenses for such engagement as a service provider instead of as an employee. Effective as of January 1, 2017, we pay Uneri Capital a monthly fee of $26,250 and a car allowance at a monthly cost of up to NIS 5,000 (approximately $1,453). The fee, and all other payments derived from a multiple of the fee that we pay Uneri Capital is paid in NIS based on the NIS/$ exchange rate at the beginning of the month in which such amounts are paid, but not lower than the exchange rate in effect on January 1, 2017. The service agreement may be terminated by either party upon 120 days' advance notice to the other party. In addition, Mr. Israel is entitled to the following additional compensation:

Retirement Grant. A retirement grant of six times the monthly fee upon termination of Mr. Israel's engagement with us, provided that the termination is not due to circumstances that do not entitle an employee to severance payments under any applicable law and/or under any judicial decision of a competent tribunal.

Annual Bonus. Annual bonus shall not exceed eight times the monthly fee, of which up to six times the monthly fee is based on measurable criteria determined by the Compensation Committee and Board of Directors and up to two times the monthly fee is based on non-measurable criteria.

Special bonus based on either a Merger Transaction, Fund Raise or a Commercialization Transaction. A special bonus equal to: (i) 3.5% of our valuation determined in a Merger Transaction for a valuation up to $30 million, plus an additional 2.0% of our valuation for the next $20 million layer of valuation (i.e., above $30 million but less than $50 million), plus an additional 1.0% of our valuation for the layer of valuation above $50 million; provided that in any event Mr. Israel will not be entitled to a bonus based on a Merger Transaction in an amount exceeding $2,000,000. A "Merger Transaction" means one or more related transactions of either: (A) sale, lease, license or any transfer of all or most of our assets or securities; (B) merger so that the shareholders holding at least 50% of our issued and outstanding share capital prior to the consummation of such transaction hold less than 50% of our issued and outstanding share capital or the share capital of the surviving company following the consummation of such transaction; (ii) 3.5% of the cumulative revenues from a Commercialization Transaction for cumulative revenues up to $30 million, plus 2.0% of cumulative revenues above $30 million but less than $50 million, plus 1.0% of cumulative revenues above $50 million. The bonus is payable for a Commercial Transaction whose value or estimated value is at least $5 million as a result of the commercialization of our products. In the event the value or estimated value of a Commercialization Transaction exceeds such amount, Mr. Israel will be entitled to an additional monthly bonus against revenues as a result of the Commercialization Transaction in the prior month. In any event Mr. Israel will not be entitled to a bonus based on a Commercialization Transaction in an amount exceeding $2,000,000. A "Commercialization Transaction" means the execution of a licensing and/or distribution agreement of our products with estimated revenues of at least $5 million. Any special bonus to be paid to Mr. Israel with respect to a Commercialization Transaction shall be subject to the limitation that any special bonuses to office holders of the Company together with any fees paid to advisors, bankers and such in connection with the Commercialization Transaction shall be in aggregate no more than 17% of the cumulative revenues from a Commercialization Transaction for cumulative revenues up to $30 million, and no more that 14% of cumulative revenues above $30 million.

For information regarding equity-based compensation awarded to Mr. Israel in 2020, see above under "Director Compensation."

C. Board Practices

Board of Directors

Our board of directors presently consists of seven directors. All of our directors also serve as directors of our subsidiaries TyrNovo and FameWave. Each of Dr. Rowinsky, Ms. Stern-Raff, Mr. Steinberg, Mr. Gagnon and Mr. Agmon qualifies as an independent director under the corporate governance standards of the NASDAQ Listing Rules and the independence requirements of Rule 10A-3 of the Exchange Act. A majority of our Board members are independent as required by the NASDAQ Listing Rules. Furthermore, our Audit Committee consists of at least three independent directors, and our Compensation Committee consists of at least two independent directors.

Our directors are elected to serve are divided into three classes with staggered three-year terms. Each class of directors consists, as nearly as possible, of one-third of the members of our board of directors (the "Board") (who are not external directors, if any were appointed), referred to as the "first class"; the "second class"; and the "third class". If the number of directors is not equally divisible by three, each of the first class and the second class will be comprised of a different number, the closest and lowest to one-third, while the third class will be comprised of the remaining directors (who are not external directors, if any were appointed). If the number of directors changes, the number of directors in each class will change in accordance with the foregoing rule. The term of one class of directors expires at each annual general meeting, at which the election (or re-election) of directors of the class whose term expired at such annual general meeting shall be for a term that expires on the date of the third annual general meeting following such election (or re-election) and until his or her respective successor has been elected and qualified. At our 2021 annual general meeting of shareholders, the appointment of the directors included in the third class (Mr. Israel and Ms. Stern-Raff) shall end. At our 2022 annual general meeting of shareholders, the appointment of the directors included in the first class (Dr. Rowinsky, Mr. Agmon and Mr. Gagnon) shall end. At our 2023 annual general meeting of shareholders, the appointment of the directors included in the second class (Messrs. Rock and Steinberg) shall end.

Our Board may appoint a director at any time to fill any vacancies until the annual meeting of our shareholders set to take place at the end of the three-year-term for the class of directors to which such director is so appointed by the Board, provided that the total number of the members of the Board serving at such time will not exceed the maximum number of directors that may serve on the Board. The shareholders may at all times, by a Special Majority (as defined below) vote of the shareholders, replace or dismiss a director (in the case of replacement, only if the appointed director is not a corporation). A director to be replaced shall be given a reasonable opportunity to address the shareholders at their meeting. The tenure of a director expires pursuant to the provisions of our amended and restated articles of association and the Companies Law, upon death or if he/she becomes incompetent, unless removed from office earlier as described above.

Under our amended and restated articles of association, the number of directors on our Board will be no less than four and no more than nine (including any external directors, to the extent that we may be required to appoint external directors in accordance with the Companies Law and any Regulations enacted thereunder). The majority of the members of the Board shall be residents of Israel, unless our center of management shall have been transferred to another country in accordance with a resolution of our Board by a majority of three quarters (75%) of the participating director votes. The number of directors that may serve on our Board of Directors under our amended and restated articles of association may be changed, at any time and from time to time, by our shareholders with a majority of (a) 75% of the voting rights participating and voting on the matter in the applicable general meeting of our shareholders and (b) more than 47.9% of all of the voting rights in Purple Biotech as of the record date established for the applicable general meeting of our shareholders ("Special Majority").

In addition, under the Companies Law, our board of directors must determine the minimum number of directors who are required to have financial and accounting expertise. Under applicable regulations, a director with financial and accounting expertise is a director who, by reason of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements. He or she must be able to thoroughly comprehend the financial statements of the company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, the board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that we require at least one director with the requisite financial and accounting expertise and that Mr. Rock, Mr. Steinberg, Ms. Stern-Raff and Mr. Gagnon are each deemed to have such expertise.

External Directors

Under the Companies Law, companies incorporated under the laws of the State of Israel that are "public companies," including companies with shares listed on NASDAQ, are required to appoint at least two external directors. However, pursuant to regulations promulgated under the Companies Law, companies with shares traded on a U.S. stock exchange, including NASDAQ, may, subject to certain conditions, "opt out" from the Companies Law requirements to appoint external directors and related Companies Law rules concerning the composition of the audit committee and compensation committee of the board of directors. In accordance with these regulations, in July 2016, we elected to "opt out" from the Companies Law requirements to appoint external directors and related Companies Law rules concerning the composition of the audit committee and compensation committee of the board of directors. Under these regulations, the exemptions from such Companies Law requirements will continue to be available to us so long as: (i) we do not have a "controlling shareholder" (as such term is defined under Section 1 of the Companies Law), (ii) our shares are traded on a U.S. stock exchange, including NASDAQ, and (iii) we comply with the director independence requirements, the audit committee and the compensation committee composition requirements, under U.S. laws (including applicable NASDAQ Rules) applicable to U.S. domestic issuers. 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.

Should any person or entity become deemed to be a controlling shareholder as defined in Section 1 of the Companies Law, then in accordance with Section 248(a) of the Companies Law, we will be required to convene a special general meeting of the shareholders at the earliest possible date, the agenda of which shall include the appointment of at least two external directors. Following such appointment, all of the external directors shall be appointed to each of our audit committee and compensation committee, and at least one external director shall be appointed to each committee of the Board of Directors authorized to exercise any of the powers of the board of directors.

Alternate Directors

Our amended and restated articles of association provide, as allowed by the Companies Law, that any director may, at all times, appoint any person (which is not a corporation) by written notice to us to serve as an alternate director at a meeting of the board of directors. Under the Companies Law, a person who is not qualified to be appointed as a director, a person who is already serving as a director or a person who is already serving as an alternate director for another director, may not be appointed as an alternate director, unless otherwise permitted by applicable law. A director who is already serving as a director may be appointed as an alternate director for a member of a committee of the board of directors so long as he or she is not already serving as a member of such committee. An appointing director may at any time cancel the appointment of an alternate director. The term of appointment of an alternate director will end if the appointing director notifies us in writing of the termination or cancellation of the appointment or if the appointing director's appointment is terminated.

Audit Committee

Under the Companies Law, the board of directors of any public company must appoint an audit committee. Companies listed on foreign stock exchanges, including NASDAQ, which have elected to "opt out" of the Companies Law requirements relating to external directors and related rules concerning the composition of the audit committee and compensation committee, such as our company (as described above), are exempt from the audit committee composition requirements under the Companies Law, but must comply with the audit committee composition requirements of the applicable foreign exchange.

Under the NASDAQ Listing Rules, we are required to maintain an audit committee consisting of at least three independent directors, within the meaning of the Exchange Act and Nasdaq Listing Rules, all of whom are financially literate and one of whom has accounting or related financial management expertise.

Audit Committee Role

Under the Companies Law, the roles of the audit committee are, among others, as follows:

- recommends to the board of directors to recommend to our shareholders to appoint and approve the compensation of the independent registered public accounting firm engaged to audit our financial statements;

- monitors deficiencies in the management of the Company, among other things, in consultation with the independent registered public accounting firm and internal auditor, and advises the board of directors on how to correct such deficiencies;

- decides whether to approve engagements or transactions that require the audit committee's approval under the Companies Law relating generally to certain related party transactions and whether such transaction is "extraordinary" or "material" under the Companies Law. The audit committee must pre-determine procedures for a competitive process, or other procedures, before approving related party transactions with controlling shareholders, even if such transactions are deemed by the audit committee not to be extraordinary transactions. This process is to be supervised by the audit committee, or any person authorized for such supervision, or via any other method approved by the audit committee;

- determines the approval process for transactions that are not negligible, as well as determine which types of non-negligible transactions would require the approval of the audit committee. Non-negligible transactions are defined as related party transactions with a controlling shareholder, or in which the controlling shareholder has a personal interest, even if they are deemed by the audit committee not to be extraordinary transactions but which have been classified by the audit committee as non-negligible transactions;

- meets and receives reports from both the internal auditors and the independent registered public accounting firm dealing with matters that arise in connection with their audits; and

- regulates the Company's rules on employee complaints, and implements a whistleblower protection plan with respect to employee complaints of business irregularities.

Our audit committee also fulfills the functions previously carried out by our former investment committee (which was disbanded), including overseeing the management and investment of our cash and cash equivalents and making investment decisions with respect to our financial assets.

In accordance with the Sarbanes-Oxley Act of 2002 and the NASDAQ Listing Rules, the audit committee is also directly responsible for the appointment, compensation and performance of our independent auditors, and pre-approves audit and non-audit services to be provided by the independent auditors. In addition, the audit committee is responsible for assisting the board of directors in reviewing our annual financial statements, the adequacy of our internal controls and our compliance with legal and regulatory requirements. The audit committee also oversees our major financial risk exposures and policies for managing such potential risks, discusses with management and our independent auditor significant risks or exposure and assesses the steps management has taken to minimize such risk.

Our board of directors has adopted an audit committee charter setting forth the responsibilities of the audit committee, which are consistent with the provisions of the Companies Law, rules and regulations of the SEC and the NASDAQ Listing Rules.

Our audit committee currently consists of Ms. Revital Stern-Raff, Mr. Steven Steinberg and Mr. Ido Agmon. Mr. Steinberg serves as the Chairman of the audit committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the NASDAQ Listing Rules. Our board of directors has determined that each of Revital Stern-Raff and Steven Steinberg are audit committee financial experts as defined by the SEC rules and all of the audit committee members have the requisite financial experience required by the NASDAQ Listing Rules.

Compensation Committee

Under the Companies Law, the board of directors of an Israeli public company is required to appoint a compensation committee in accordance with the requirements set forth in the Companies Law. Companies listed on foreign stock exchanges, including NASDAQ, which have elected to "opt out" of the Companies Law requirements relating to external directors and related rules concerning the composition of the audit committee and compensation committee, such as our company (as described above), are exempt from the compensation committee composition requirements under the Companies Law, but must comply with the compensation committee composition requirements of the applicable foreign exchange.

In accordance with the Companies Law, the roles of the compensation committee are, among others, as follows:

- to recommend to the board of directors (i) the compensation policy for directors and officers, (ii) once every three years, whether the compensation policy that had been approved should be extended for a period of more than three years; and (iii) updates to the compensation policy, from time to time. In addition, the compensation committee is required to periodically examine the implementation of the compensation policy;

- to decide whether to approve the terms of office and employment of directors and officers that require approval of the compensation committee; and

- to decide whether the compensation terms of the chief executive officer of Purple Biotech which were determined pursuant to the compensation policy need not be brought for approval of the shareholders because it will harm the ability to engage with the chief executive officer.

In addition to the roles mentioned above our compensation committee also makes recommendations to our board of directors regarding the awarding of employee equity grants.

Our board of directors has adopted a compensation committee charter setting forth the responsibilities of the compensation committee, which are consistent with the provisions of the Companies Law, rules and regulations of the SEC and the NASDAQ Listing Rules.

Our compensation committee currently consists of Mr. Steven Steinberg and Mr. Ido Agmon. Mr. Agmon serves as the Chairman of the compensation committee.

Compensation Policy

Under the Companies Law, Israeli public companies must adopt a compensation policy with respect to the terms of service and employment of their directors and officers. The compensation policy must be approved by the board of directors (after considering the recommendations of the compensation committee) and subject to limited exceptions, by the shareholders. Shareholder approval requires one of the following: (i) the majority of shareholder votes counted at general meeting including the majority of all of the votes of those shareholders who are non-controlling shareholders and do not have a personal interest in the approval of the compensation policy, who participate at the meeting (excluding abstentions) or (ii) the total number of votes against the proposal among the shareholders mentioned in paragraph (i) does exceed two percent (2%) of the voting rights in the company, referred to as the "Special Majority for Compensation." Under special circumstances, the board of directors may approve the compensation policy despite the objection of the shareholders on the condition that the compensation committee and then the board of directors decide, on the basis of detailed arguments and after discussing again the compensation policy, that approval of the compensation policy, despite the objection of the meeting of shareholders, is for the benefit of the company.

Our Compensation Policy must be reviewed from time to time by our Compensation Committee and Board of Directors, to ensure its alignment with our compensation philosophy and to consider its appropriateness for the Company. Pursuant to the Israeli Companies Law, our Compensation Policy must generally be re-approved once every three years by the Board of Directors, after considering the recommendations of the Compensation Committee, and by the shareholders by the Special Majority for Compensation, as detailed above. Any amendment to the Compensation Policy requires the same approvals.

On August 6, 2020, our shareholders approved our current compensation policy for executive officers and directors (the "Compensation Policy"). The Compensation Policy will not, on its own, grant any rights to our directors or officers. The Compensation Policy includes both long-term and short-term compensation elements.

In general, compensation for officers will be examined while taking into consideration the following parameters, including, among others (i) education, qualifications, expertise, tenure (with us in particular, and in the officer's profession in general), professional experience and achievements of the officer; (ii) the fulfilment by the officer of the targets set for him/her, if relevant; (iii) the officer's position, the scope of his/her responsibility and previous wage agreements that were signed with the officer; and (iv) the ratio between the total cost of the proposed engagement terms of an officer and the total cost of the wages for all of our other employees, officers and contractors, and in particular compared to the average or median wage of such employees, officers and contractors and the effect of this ratio and difference, if any, on labor relations.

In adopting our initial Compensation Policy, we considered feedback we received from shareholders regarding corporate governance "best practices" for companies of a similar size, scope of business, and life-cycle. Subsequently, we adopted the Compensation Policy to better align and to further improve the link between the long-term interests of the participants of the compensation system with those of the shareholder. We expect that we will continue to monitor the regulatory environment and if required, to solicit feedback from our shareholders in the future to ensure that this link is maintained and continuously strengthened.

In adopting our initial Compensation Policy and its subsequent amendment and renewal, our Compensation Committee and Board of Directors considered numerous factors, including the relevant matters and provisions set forth in the Israeli Companies Law, and reviewed various data and other information they deemed relevant, with the advice and assistance of legal and other advisors. They also used benchmark studies of peer companies prepared for us by outside consultants to determine that the various compensation elements included in the Compensation Policy are in line with market practice. Our Compensation Committee expects to conduct these analyses and benchmarks pay for executives at least once every three years. The benchmark group comprised a selection of companies chosen to reflect the competitive environment in which we operate. These companies were selected according to criteria such as revenues, market capitalization, business type, geographic location, and size.

Our Compensation Policy is intended to strike a balance between short and long-term performance incentives for the executives in a way that links pay to performance of our executive officers' interests with those of the Company and our shareholders. We believe that it allows us to provide meaningful incentives that reflect both our short- and long-term goals and performance, as well as our executive officers' individual performance and impact on shareholder value, while providing compensation that is competitive in the global marketplace in which we recruit talent and designed to reduce incentives to take excessive risks.

The brief overview above is qualified in its entirety by reference to the full text of our Compensation Policy, which is attached as an exhibit to this Annual Report on Form 20-F.

Nominations Committee

In September 2020, our Board of Directors established a non-independent nominations committee, whose role is (among other things) to identify, review and evaluate candidates to serve as members of the Board, consistent with criteria approved by the Board, recommend to the Board of Directors nominees for election as directors of the Company, and review and evaluate incumbent members of the Board. Our nominations committee currently consists of Dr. Eric Rowinsky, Mr. Ido Agmon and Mr. Simcha Rock. Eric Rowinsky serves as the Chairman of the nominations committee.

Internal Auditor

Under the Companies Law, the board of directors of a public company must appoint an internal auditor based on the recommendation of 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 a related party or an office holder or a relative of a related party or of an office holder, nor may the internal auditor be the company's independent auditor or the representative of the same. A "related party" is defined in the Companies Law as (i) a holder of 5% or more of the issued share capital or voting power in a company, (ii) any person or entity 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. In July 2016, our Board of Directors, following the recommendation of our Audit Committee, resolved to appoint as the Company's internal auditor, Mr. Yisrael Gewirtz, a partner at Fahn Kanne Control Management Ltd., a member firm of Grant Thornton International.

Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law

Fiduciary Duties of Office Holders

The Companies Law imposes a duty of care and a fiduciary duty on all office holders of a company. The duty of care of an office holder is based on definition of negligence under the Israeli Torts Ordinance (New Version) 5728-1968. This duty of care requires an office holder to act with the degree of proficiency 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 business advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to such action.

The fiduciary duty incumbent on an office holder requires him or her 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 interest between the performance of his or her duties in 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 for the purpose of gaining a personal advantage 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 fiduciary duty, 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 time before the approval of such act. Any such approval is subject to the terms of the Companies Law, setting forth, among other things, the appropriate corporate bodies of the company entitled to provide such approval, and the methods of obtaining such approval.

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. An interested office holder's disclosure must be made promptly and, in any event, 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 an extraordinary transaction.

Under the Companies Law, once an office holder has complied with the above disclosure requirement, a company may approve a transaction between the company and the office holder or a third party in which the office holder has a personal interest. However, a company may not approve a transaction or action that is not to the company's benefit.

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, which is not an extraordinary transaction, requires approval by the board of directors. The Companies Law provides that such a transaction, which is not an extraordinary transaction, may be approved by the board of directors, unless provided otherwise in the company's articles of association. Our amended and restated articles of association provide that transactions in which officers have a personal interest that are not extraordinary transactions can be approved by the joint approval of our chief executive officer and chief financial officer (unless either of them has a personal interest in such transaction, in which case by one of our directors who does not have a personal interest in such transaction appointed by our board of directors for such purpose instead of such interested officer). If the transaction considered is an extraordinary transaction with either an office holder or with a third party in which the office holder has a personal interest, then, pursuant to the Companies Law, audit committee approval is required prior to approval by the board of directors. For the approval of compensation arrangements with directors and executive officers, see below "Compensation of Directors and Executive Officers."

Any persons who have a personal interest in the approval of a transaction (except for a transaction with an office holder or with a third party in which the office holder has a personal interest that is not an extraordinary transaction) that is brought before a meeting of the board of directors or the audit committee may not be present at the meeting or vote on the matter. However, if the chairman of the board of directors or the chairman of the audit committee has determined that the presence of an office holder with a personal interest is required, such office holder may be present at the meeting for the purpose of presenting the matter. Notwithstanding the foregoing, a director who has a personal interest may be present at the meeting and vote on the matter if a majority of the directors or members of the audit committee have a personal interest in the approval of such transaction. If a majority of the directors at a board of directors meeting have a personal interest in the transaction, such transaction also requires approval of the shareholders of 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 the interest of any other corporate body in which the person or such person's relative is a director or general manager, a 5% shareholder or holds 5% or more of the voting rights, or has the right to appoint at least one director or the general manager, but excluding a personal interest stemming solely from the fact of holding shares in the company. A personal interest also includes (1) a personal interest of a person who votes according to a proxy of another person, including in the event that the other person has no personal interest, and (2) a personal interest of a person who gave a proxy to another person to vote on his or her behalf regardless of whether the discretion of how to vote lies with the person voting or not.

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 may have a material impact on the company's profitability, assets or liabilities.

Disclosure of Personal Interests of a Controlling Shareholder and Approval of Transactions

The Companies Law also requires that a controlling shareholder 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 controlling shareholder's disclosure must be made promptly and, in any event, no later than the first meeting of the board of directors at which the transaction is considered. Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest, and the terms of engagement of the company, directly or indirectly, with a controlling shareholder or a controlling shareholder's relative (including through a corporation controlled by a controlling shareholder), regarding the company's receipt of services from the controlling shareholder, and if such controlling shareholder is also an office holder of the company, regarding his or her terms of employment, require the approval of each of (i) the audit committee or the compensation committee with respect to the terms of the engagement of the company, (ii) the board of directors and (iii), unless exempted under the regulations promulgated under the Companies Law, the shareholders, in that order. In addition, the shareholder approval must fulfill one of the following requirements:

- a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or
- the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than 2% of the voting rights in the company.

In addition, 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 the abovementioned approval every three years, however, such transactions not involving the receipt of services or compensation can be approved for a longer term, provided that the audit committee determines that such longer term is reasonable under the circumstances.

The Companies Law requires that every shareholder that participates, in person, by proxy or by voting instrument, in a vote regarding a transaction with a controlling shareholder or in which such has a personal interest, must indicate in advance or in the ballot whether or not that shareholder has a personal interest in the vote in question. Failure to so indicate will result in the invalidation of that shareholder's vote. For more information regarding exemptions from shareholder approval for extraordinary transactions with a controlling shareholder, see "Item 10 – Additional Information – B. Memorandum and Articles of Association – Board of Directors."

Compensation of Directors and Executive Officers

Directors. Under the Companies Law, the compensation of our directors with respect to their service as a director, as well as their engagement in other roles (if the director is so engaged) 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 compensation of a director that is inconsistent with our duly approved compensation policy (or approve compensation prior to the approval of a new compensation policy upon expiration of the term of the previous compensation policy), provided that those provisions that must be included in and considered when determining the compensation policy according to the Companies Law have been considered by the compensation committee and board of directors and shareholder approval is required by the Special Majority for Compensation, as described above.

Executive Officers Other Than the Chief Executive Officer. The Companies Law requires the compensation of a public company's executive officers (other than the chief executive officer) who are not directors to be approved by, first, the compensation committee, second, by the company's board of directors and third, if such compensation arrangement is inconsistent with the company's duly approved compensation policy(or if compensation is approved prior to the approval of a new compensation policy upon expiration of the term of the previous compensation policy), also by the company's shareholders by the Special Majority for Compensation as discussed above provided that those provisions that must be included in, and must be considered while determining, the compensation policy according to the Companies Law have been considered. However, if the shareholders of the company do not approve a compensation arrangement with an executive officer that is inconsistent with the company's stated compensation policy, the compensation committee and board of directors may, in special circumstances, override the shareholders' decision if each of the compensation committee and the board of directors discuss the arrangement again, analyze the shareholders' objections and provide detailed reasons for their decision. An amendment to an existing arrangement with an office holder who is not a director requires only the approval of the compensation committee if the compensation committee determines that the amendment is not material relative to the existing arrangement. However, pursuant to the regulations promulgated under the Companies Law, non-material amendments to the compensation of a public company's executive officers (who are subordinate to the chief executive officer) shall not require the approval of the compensation committee and may be approved by the chief executive officer of the company if (i) the company's compensation policy has established that such amendments within the parameters established in the compensation policy may be approved by the chief executive officer, and (ii) the compensation is consistent with the company's compensation policy.

Chief Executive Officer. The compensation paid to a public company's chief executive officer is required to be approved by, first, the company's compensation committee; second, the company's board of directors, and, unless exempted under the regulations promulgated under the Companies Law, by the company's shareholders by the Special Majority for Compensation as discussed above. However, if the shareholders of the company do not approve the compensation arrangement with the chief executive officer who is not a director at the company, the compensation committee and board of directors may, in special circumstances, override the shareholders' decision if each of the compensation committee and the board of directors discuss the arrangement again, analyze the shareholders' objection and provide detailed reasons for their decision. The renewal or extension of the engagement with a public company's chief executive officer need not be approved by the shareholders of the company if the terms and conditions of such renewal or extension are no more beneficial than the previous engagement or there is no substantial difference in the terms and conditions under the circumstances, and the terms and conditions of such renewal or extension are in accordance with the company's compensation policy.

The compensation committee and board of directors approval should be in accordance with the company's duly approved 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 those provisions that must be considered and included in the compensation policy according to the Companies Law and that shareholder approval was obtained by the Special Majority for Compensation as discussed above. The compensation committee may waive the shareholder approval requirement with regards to the approval of the initial engagement terms of a candidate for the chief executive officer position, if they determine that the compensation arrangement is consistent with the company's stated compensation policy, and that the chief executive officer did not have a prior business relationship with the company or a controlling shareholder of the company and that subjecting the approval of the engagement to a shareholder vote would impede the company's ability to employ the chief executive officer candidate.

The engagement with a public company's chief executive officer or a director need not be approved by the shareholders of the company with respect to the period from the commencement of the engagement until the next shareholder meeting convened by the company, if the terms and conditions of such engagement were approved by the compensation committee and the board of directors of the company, the terms and conditions of such engagement are in accordance with the company's compensation policy approved in accordance with the Companies Law, and if the terms and conditions of such engagement are no more beneficial than the terms and conditions of the person previously serving in such role or there is no substantial difference in the terms and conditions of the previous engagement versus the new one under the circumstances, including the scope of engagement.

Duties of Shareholders

Under the Companies Law, a shareholder has a duty to refrain from abusing its power in the company and to act in good faith and in an acceptable 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 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.

The remedies generally available upon a breach of contract will also apply to a breach of the shareholder duties mentioned above, and in the event of discrimination against other shareholders, additional remedies are available to the injured shareholder.

In addition, any controlling shareholder, any shareholder that knows that its 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 any other power with respect to a company, is under a duty to act with fairness towards the company. The Companies Law does not describe 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, taking the shareholder's position in the company into account.

Exculpation, Insurance and Indemnification of Directors and Officers

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of a fiduciary duty. 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 its articles of association. Our amended and restated articles of association include such a provision. The company may not exculpate in advance a director from liability arising out of breach of duty of care with respect to a prohibited dividend or distribution to shareholders.

Under the Companies Law and the Securities Law, 5738 – 1968 ("Securities Law") a company may indemnify an office holder in respect of the following liabilities, payments and expenses incurred for acts performed by him or her as an office holder, either in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- a monetary liability incurred by or 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, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;
- reasonable litigation expenses, including reasonable attorneys' fees, incurred by the office holder 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 or in connection with a monetary sanction;

- a monetary liability imposed on him or her in favor of a payment for a breach offended at an Administrative Procedure (as defined below) as set forth in Section 52(54)(a)(1)(a) to the Securities Law;

- expenses associated with an Administrative Procedure conducted regarding an office holder, including reasonable litigation expenses and reasonable attorneys' fees; 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.

An "Administrative Procedure" is defined as a procedure pursuant to chapters H3 (Monetary Sanction by the Israeli Securities Authority), H4 (Administrative Enforcement Procedures of the Administrative Enforcement Committee) or I1 (Arrangement to prevent Procedures or Interruption of procedures subject to conditions) to the Securities Law.

Under the Companies Law and the Securities Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of a fiduciary duty 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;

- a monetary liability imposed on the office holder in favor of a third party;

- a monetary liability imposed on the office holder in favor of an injured party at an Administrative Procedure pursuant to Section 52(54)(a)(1)(a) of the Securities Law; and

- expenses incurred by an office holder in connection with an Administrative Procedure, including reasonable litigation expenses and reasonable attorneys' fees.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of fiduciary duty, except for indemnification and insurance for a breach of the fiduciary duty 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 prejudice the company;

- a breach of 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, monetary sanction or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders must be approved by the compensation committee and the board of directors and, with respect to directors or controlling shareholders, their relatives and third parties in which such controlling shareholders have a personal interest, also by the shareholders.

The compensation committee may approve the inclusion of each office holder under the coverage of our directors and officers insurance policy without the need for shareholder approval, if it determines that, pursuant to the leniencies set forth in the Relief Regulations, the provision of such insurance coverage to the office holders under our directors and officers liabilities insurance policy is being granted on market terms, and is not likely to have a material adverse effect on our profits, assets or obligations, and is consistent with our Compensation Policy which was approved by our shareholders in accordance with the Companies Law.

Our amended and restated articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by law. Our office holders are currently covered by a directors' and officers' liability insurance policy within the parameters set forth in our Compensation Policy.

Our audit committee and board of directors approved the issuance of letters of indemnity (the "Indemnity Letters") to our office holders pursuant to which we agreed to indemnify such office holders, including an undertaking in advance for such indemnification. The Indemnity Letters also received the approval of our shareholders. According to the Indemnity Letters, the total accumulative sum of indemnification paid by us to all our office holders that were issued by Purple Biotech will not exceed a sum equal to 25% of our equity attributed to our shareholders according to our latest audited or reviewed consolidated financial statements, as the case may be, as of the date of indemnification. The payment of the indemnity sum will not prejudice the right of office holders to receive insurance coverage benefits. Once we have paid indemnity sums to our office holders at the maximum indemnity sum, we will not bear additional indemnity sums unless the payment of these additional sums is approved by authorized corporate bodies according to the law applicable at the time of payment of the additional indemnity sums, and subject to an amendment in our articles of association if required by applicable law at such time.

In addition, we have entered into 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 law, subject to limited exceptions, and undertaking to indemnify them to the fullest extent permitted by law, subject to limited exceptions, including with respect to liabilities resulting from our Registration Statements, to the extent that these liabilities are not covered by insurance. This indemnification is limited to events determined as foreseeable by the board of directors based on our activities, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances. The maximum aggregate amount of indemnification that we may pay to our office holders based on such indemnification agreement is with respect to all permitted indemnification, including in connection with a public offering of our securities, an amount equal to 25% of our shareholders' equity on a consolidated basis, based on our most recent financial statements made publicly available before the date on which the indemnification payment was made. Such indemnification amounts are in addition to any insurance amounts. Each office holder who agrees to receive this letter of indemnification also gives his approval to the termination of all previous letters of indemnification that we have provided to him or her in the past, if any.

We expect to indemnify our officers and directors for obligations, including the deductibles for our directors' and officers' liability insurance policy, and we may be required to pay costs and expenses they may incur related to the 2015 Motion and the 2017 Motions described in "Item 8. Financial Information – A. Financial Statements and Other Financial Information – Legal Proceedings", pursuant to the letters of indemnification issued to our directors and officers. In addition, we expect to indemnify Hadas Reuveni for obligations, including the deductibles for our directors' and officers' liability insurance policy, and we may be required to pay costs and expenses she may incur related to the BIRAD claim described in "Item 8. Financial Information – A. Financial Statements and Other Financial Information – Legal Proceedings", pursuant to the letter of indemnification issued to her. To our knowledge, other than with respect to the foregoing proceedings, there is no previous or pending litigation or proceedings against any of our office holders as to which indemnification is being, or may be sought, nor are we aware of any other pending or threatened litigation or proceeding that may result in claims for indemnification by any office holder.

Insofar as indemnifications for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

D. Employees

As of December 31, 2020, the Company had employees (including consultants on a full-time basis) as follows: (i) six in business development, general and administrative roles; and (ii) seven in research and development roles. All of such employees were located in Israel other than one employee in research and development, who is located in the United States.

As of December 31, 2019, the Company had employees (including consultants on a full-time basis) as follows: (i) six in business development, general and administrative roles; and (ii) three in research and development roles. All of such employees were located in Israel.

As of December 31, 2018, the Company had employees (including consultants on a full-time basis) as follows: (i) six in business development, general and administrative roles; and (ii) four in research and development roles. All of such employees were located in Israel.

While none of our employees is party to a collective bargaining agreement, in Israel we are subject to certain labor statutes and national labor court precedent rulings, as well as to certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations including the Industrialists' Associations. These provisions of collective bargaining agreements are applicable to our Israeli employees by virtue of extension orders issued in accordance with relevant labor laws by the Israeli Ministry of Labor and Welfare, and which apply such agreement provisions to our employees even though they are not directly part of a union that has signed a collective bargaining agreement. The laws and labor court rulings that apply to our employees principally concern the minimum wage laws, procedures for dismissing employees, determination of severance pay, leaves of absence (such as annual vacation or maternity leave), sick pay and other conditions for employment. The extension orders which apply to our employees principally concern the requirement for length of the workday and workweek, mandatory contributions to a pension fund, annual recreation allowance, travel expenses payment and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

Israeli law generally requires severance pay, which may be funded by managers' insurance and/or a pension fund described below, upon the retirement or death of an employee or termination of employment without cause (as defined in the law). Furthermore, Israeli employees and employers are required to pay predetermined sums to the National Insurance Institute, which is similar to the United States Social Security Administration. Such amounts also include payments for national health insurance. A general practice also followed by us is the contribution of funds on behalf of most of our employees either to a fund known as managers' insurance, to a pension fund or to a combination of both.

We have never experienced labor-related work stoppages or strikes and believe that our relations with our employees are satisfactory.

E. Share Ownership

As of March 7, 2021, no officer or director beneficially owned 1% or more of our outstanding ordinary shares and all officers and directors as a group (12 persons) beneficially owned less than 1% of our ordinary shares.

2016 Equity-Based Incentive Plan

On April 18, 2016, we adopted the Purple Biotech Ltd. 2016 Equity-Based Incentive Plan, or the 2016 Equity Incentive Plan. The 2016 Equity Incentive Plan provides for the grant to our directors, officers, employees and consultants and to the directors, officers, employees and consultants of our subsidiaries and affiliates, of equity-based incentive awards, including, amongst others, options, restricted share units (RSUs), restricted shares, with either our ordinary shares or ADSs underlying the applicable award. The 2016 Equity Incentive Plan provides for awards to be granted at the determination of our board of directors (who is entitled to delegate its powers under the 2016 Equity Incentive Plan to the compensation committee or audit committee of our board of directors) in accordance with applicable laws. The exercise price and vesting period of awards are determined by our board of directors. The number of ordinary shares currently reserved for the grant of awards under the 2016 Equity Incentive Plan is 15,000,000 ordinary shares. Our board of directors may, subject to any other approvals required under any applicable law, increase or decrease the number of ordinary shares to be reserved under the 2016 Equity Incentive Plan. As of December 31, 2020, non-tradable options to purchase 4,986,144 ordinary shares and 3,390,000 RSUs were outstanding under the 2016 Equity Incentive Plan.

The 2016 Equity Incentive Plan will be effective until the earliest of (a) its cancellation by our board of directors and (b) April 18, 2026. Nevertheless, awards granted prior to the 2016 Equity Incentive Plan's expiration date, whether vested or not vested up to that date, will remain effective and will not expire prior to their expiration date as set forth in the notice of grant of award (but in any event not in excess of 10 years from the grant date).

Upon termination of engagement with the Company for any reason, other than in the event of death or for cause, all unvested options will expire and all vested options at time of termination will generally be exercisable within up 12 months after the date of such termination, unless otherwise determined by the board of directors (or the committee, as applicable), subject to the terms of the 2016 Equity Incentive Plan and the governing award agreement. If we terminate a grantee for cause (as defined in the 2016 Equity Incentive Plan) the grantee's right to exercise all vested and unvested options granted to him will expire immediately, unless otherwise determined by the board of directors (or the committee, as applicable). Upon termination of engagement with the Company due to death, all the vested options at the time of termination will be exercisable by the grantee's heirs or estate, for one year from the date of death, unless otherwise determined by the board of directors (or the committee, as applicable), subject to the terms of the 2016 Equity Incentive Plan and the governing award agreement.

The 2016 Equity Incentive Plan enables us to grant awards through one of the following Israeli tax programs, at our discretion and subject to the applicable legal limitations: (a) according to section 102 of the Israeli Income Tax Ordinance [New Version], 5721-1961 (the "the Israeli Income Tax Ordinance"), through a program with a trustee that is appointed by us, (b) according to section 102 of the Israeli Income Tax Ordinance, without a trustee, or (c) according to the provisions of section 3(9) in the Israeli Income Tax Ordinance. The 2016 Equity Incentive Plan also enables us to grant options as Incentive Stock Options for U.S. tax purposes.

The 2016 Equity Incentive Plan includes directives for protecting the option holders during the exercise period with respect to distribution of bonus stock, issue of rights, splitting or consolidating our share capital and dividend distribution. We are entitled at our sole discretion, to change the terms of the 2016 Equity Incentive Plan and/or replace it and/or terminate it regarding future grants at any time, as we deem appropriate. We are also entitled to change the terms of 2016 Equity Incentive Plan regarding grants that were granted to the grantees, provided that the terms of the options which were already granted will not be changed in a way that may materially impair the rights of the grantees, without the consent of award grantees holding a majority in interest of the awards so affected, and in the event that such consent is obtained, all awards so affected shall be deemed amended, and the holders thereof shall be bound, as set forth in such consent. Our board of directors will determine, at its sole discretion, if a certain change may materially impair the rights of the grantee.

The 2016 Equity Incentive Plan is administered by our board of directors, regarding the granting of awards and the terms of award grants, including exercise price, method of payment, vesting schedule, acceleration of vesting and the other matters necessary in the administration of such plan. Awards granted under the 2016 Equity Incentive Plan to eligible Israeli employees, officers and directors are granted under Section 102 of the Israel Income Tax Ordinance, pursuant to which the awards or the ordinary shares (or ADSs in accordance with a ruling from the Israel Tax Authority dated June 19, 2016, or Tax Ruling) issued upon their exercise must be allocated or issued to a trustee and be held in trust for two years from the date upon which such awards were granted in order to benefit from the provisions of Section 102. Under Section 102, any tax payable by a grantee from the grant or exercise of the awards is deferred until the transfer of the awards or ordinary shares (or ADSs, in accordance with the Tax Ruling) by the trustee to the grantee or upon the sale of the awards or ordinary shares (or ADSs, in accordance with the Tax Ruling), and gains may qualify to be taxed as capital gains at a rate equal to 25%, subject to compliance with specified conditions.

Form S-8 registration statements

On May 20, 2016, we filed a registration statement on Form S-8 under the Securities Act to register 600,000 of our ordinary shares issued or reserved to be issued under our 2016 Equity Incentive Plan, on June 6, 2017, we filed a registration statement on Form S-8 under the Securities Act to register additional 1,900,000 of our ordinary shares issued or reserved to be issued under our 2016 Equity Incentive Plan, on March 28, 2019, we filed an additional registration statement on Form S-8 under the Securities Act in order to register an additional 5,000,000 of our ordinary shares issued or reserved to be issued under the Plan, and on May 18, 2020, we filed an additional registration statement on Form S-8 under the Securities Act in order to register an additional 7,500,000 of our ordinary shares issued or reserved to be issued under the Plan. We intend to file one or more additional registration statements on Form S-8 under the Securities Act to register our ordinary shares issued or reserved to be issued under the 2016 Equity Incentive Plan. The registration statements on Form S-8 become effective automatically upon filing. Ordinary shares issued upon exercise of a share option or other award and registered pursuant to the Form S-8 registration statement will, subject to vesting provisions and Rule 144 volume limitations applicable to our affiliates, be available for sale in the open market immediately unless they are subject to any contractual lockup lock-up or, if subject to a contractual lock-up, immediately after the contractual lock-up period expires.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of Purple Biotech's ordinary shares as of March 7, 2021 by each person or entity known by us to beneficially own 5% or more of Purple Biotech's outstanding ordinary shares.

The beneficial ownership of Purple Biotech's ordinary shares in this table is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. For purposes of the table below, we deem ordinary shares issuable pursuant to options or warrants that are currently exercisable or exercisable within 60 days of March 7, 2021, if any, to be outstanding and to be beneficially owned by the person holding the options or warrants for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. The percentage of ordinary shares beneficially owned is based on 175,105,742 ordinary shares (not including 1 share held in treasury). Each one (1) ADS held represents ten (10) ordinary shares. The data presented is based on information provided to us by the holders, or disclosed in public regulatory filings in the U.S. or Israel, in accordance with applicable law.

None of our shareholders has different voting rights from other shareholders. To the best of our knowledge, we are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company. Unless otherwise noted below, all references to "ordinary shares" refers to ordinary shares of Purple Biotech.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percentage**
5% or greater shareholders		
CVI Investments, Inc.[(1)]	13,488,880	7.2%

(1) Based solely on a Schedule 13G/A filed by CVI Investments, Inc. ("CVI Investments") and Heights Capital Management, Inc. ("Heights Capital") with the SEC on February 16, 2021, includes ordinary warrants to purchase 1,348,888 ADSs. According to the Schedule 13G/A, Heights Capital, which serves as the investment manager to CVI Investments, may be deemed to be the beneficial owner of all securities owned by CVI Investments, and as such may exercise voting and dispositive power over these shares. Each of CVI Investments and Heights Capital disclaimed any beneficial ownership of any such securities, except for their pecuniary interest therein.

Except as indicated in footnotes to this table, we believe that the shareholder named in this table has sole voting and investment power with respect to all shares shown to be beneficially owned by it, based on information provided to us by such shareholder or otherwise disclosed by them in public filings.

Changes in Percentage Ownership by Major Shareholders

To our knowledge, the only significant changes in the percentage ownership held by our more than 5% shareholders as reported in our Annual Reports on Form 20-F during the past three years are as follows: (i) the ownership percentage of Goldman Hirsch Partners Ltd. decreased to under 5% in January 2018, (ii) the ownership percentage of Rosalind Master Fund L.P. increased to 9.8% in January 2018 and decreased to under 5% in May 2018, (iii) the ownership percentage of Empery Asset Management, LP increased to 8.9% in January 2019 and decreased to under 5% in 2020, (iv) the ownership percentage of Sabby Volatility Warrant Master Fund, Ltd. increased to 9.8% in June 2018, decreased to under 5% in January 2019, increased to 8.8% in January 2019, and decreased to under 5% in 2020, (v) the ownership percentage of M. Arkin Ltd. increased to 11.0% in January 2020 and decreased to under 5% in 2020, (vi) the ownership percentage of OrbiMed Israel Partners Limited Partnership increased to 9.9% in January 2020 and decreased to under 5% in 2020, (vii) the ownership percentage of Pontifax Group increased to 9.9% in January 2020 and decreased to under 5% in 2020, (viii) the ownership percentage of Armistice Capital Master Fund LLC increased to 5% in June 2018, decreased to under 5% in June 2018, increased to 5% in March 2020 and decreased to under 5% in June 2020, and (viii) the ownership percentage of CVI Investments Inc. increased to 5% in March 2020 and increased to 7.25% in 2020.

Acquisition of FameWave – Voting and Shareholder's Undertaking

In connection with our acquisition of FameWave in January 2020, each of the selling FameWave shareholders, including the investors in the concurrent private placement ADS issuance, has represented to us that other than the applicable voting undertaking and the Registration Rights Agreement that was entered into at the closing of the FameWave Transaction, such party is not, and will not be, a party to any agreement or arrangement, whether written or oral, with us, any of the our officers or shareholders or a corporation in which our officers or shareholders are an Interested Party (as defined in the Companies Law), regulating the management of the Company, the shareholders' rights in the Company, the transfer of shares in the Company, including any voting agreements, shareholder agreements or any other similar agreement even if its title is different or has any other relations or agreements with any of our shareholders, directors or officers. In addition, each of the investment funds and any FameWave shareholders that signed the Registration Rights Agreement in connection with the FameWave Transaction, entered into the Shareholder's Undertaking, which amongst other matters, contains undertakings of the shareholder not to seek to become part of a bloc of shares of the Company which would necessitate a special tender offer under the Companies Law, or would otherwise seek to effect a change of control in the Company. Furthermore, to the best of our knowledge it is the intention of all of the investment funds and the other FameWave shareholders to be passive unaffiliated shareholders of the Company. For additional Information on the Acquisition Agreement in connection with the FameWave transaction, see "Item 10 – Additional Information – C. Material Contracts – FameWave Acquisition Agreement." For additional Information on the Voting and Shareholder's Undertaking, see "Item 10 – Additional Information – C. Material Contracts – FameWave Acquisition Agreement. – Voting and Shareholder's Undertaking."

Record Holders

The Bank of New York Mellon, or BNY, is the holder of record for our ADR program, pursuant to which each ADS represents ten ordinary shares. As of March 7, 2021, BNY held 160,461,210 ordinary shares representing 91.6% of the outstanding ordinary shares at that date. Certain of these ordinary shares were held by brokers or other nominees. As a result, the number of holders of record or registered holders in the United States is not representative of the number of beneficial holders or of the residence of beneficial holders.

B. Related Party Transactions

FameWave

As part of the transaction to acquire 100% of FameWave from its shareholders in January 2020, we provided a loan to FameWave of up to approximately $2 million to pay cCAM BioTherapeutics Ltd. ("cCAM"), a wholly owned subsidiary of Merck Sharp and Dohme Corp., known as "MSD" in Israel, which discovered CM24, for the return of the intellectual property rights to CM24 to FameWave, and to repay certain loans which were provided by FameWave's previous shareholders to FameWave to conduct business pursuant to the approved business budget. Following closing of the acquisition of FameWave in January 2020, this loan became an intercompany loan between Purple Biotech and FameWave.

In addition, Purple Biotech provides services to FameWave (including research and development services, corporate management, business development services, accounting services, legal services and others) and FameWave reimburses Purple Biotech at the rate of cost plus 5% for these services.

TyrNovo

Purple Biotech and TyrNovo have entered into a formal arm's length transaction services agreement pursuant to which each party provides the other party services specified in the agreement (including research and development services, corporate management, business development services, accounting services, legal services and others) and the receiving party reimburses the other party at a rate of cost plus 5% for these services.

Agreements with Officers

We have entered into agreements with each of our executive officers. See "Item 6. Directors, Senior Management and Employees – B. Compensation".

We have granted exemption and indemnification letters to our officers and directors. See "Item 6. Directors, Senior Management and Employees - C. Board Practices - Exculpation, Insurance and Indemnification of Directors and Officers."

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

See Item 18.

Legal Proceedings

From time to time, we may become party to legal proceedings and claims in the ordinary course of business or otherwise.

2015 Motion to Approve a Class Action in Israel

On December 3, 2015, we announced that we received a lawsuit and motion to approve the lawsuit as a class action lawsuit pursuant to the Class Action Lawsuits Law 5766-2006 (the "2015 Motion") which was filed against us and our directors at the Tel Aviv District Court (Economic Division). The 2015 Motion is with respect to asserted claims for damages to the holders of our securities listed on the Tel Aviv Stock Exchange, arising due to the public offering of our initial public offering of our securities in the U.S. during November 2015. In the 2015 Motion it was claimed that the class the petitioners are seeking to represent includes anyone holding our shares at the start of trading on November 22, 2015 exclusive of the respondents and/or anyone acting on their behalf and/or any affiliates thereof and excluding anyone whose rights to our shares derive from ADS certificates issued in the U.S to such extent as derived therefrom; and any holders of our Series 2 TASE listed warrants as of the start of trading on November 22, 2015, exclusive of the respondents and/or anyone acting on their behalf and/or any affiliates thereof (the "Purported Class"). The total amount claimed from all defendants, if the 2015 Motion is certified as a class action, as set forth in the motion is approximately NIS 16.4 million (approximately $4.3 million). In addition to this amount, the petitioners in the motion are seeking remedies in order to redress discrimination against the Purported Class owing to the dilution caused by the public offering, including the possibility that the Purported Class should be awarded from us amounts reflecting the losses of the Purported Class from a possible price increase in our shares following the announcement of the Phase III clinical trial results.

We announced that we reject the claims asserted in the 2015 Motion and delivered our response to the court, and a preliminary hearing was held by the court on September 12, 2016. At such hearing the court determined that certain claims of the petitioners in connection with alleged personal interests by affiliates of ours in connection with the public offering of our initial public offering of our securities in the U.S. during November 2015 are not part of the grounds for the 2015 Motion and no remedies shall be sought by the petitioners in connection therewith. The parties subsequently filed various motions in connection with discovery. On October 24, 2017, the court issued a ruling to stay proceedings in this matter until January 15, 2018 due to the ongoing ISA Investigation. This stay was subsequently extended by the court, which ruled that the stay of proceedings shall remain in place pending delivery of a notice to the court by the ISA with respect to an update on the ISA Investigation. At the request of the ISA, this stay was subsequently extended several times by the court. Following approval of the Enforcement Arrangement in connection with the ISA Investigation (see below), the stay was lifted. An evidentiary hearing is scheduled for July 8, 2021.

On November 8, 2016, a shareholder of ours submitted a request to the court in connection with the 2015 Motion to be excluded from the Purported Class and claiming to have independent causes of action and claims of approximately NIS 1 million (the "Petition to Exclude"). We responded to the court, and, amongst other arguments, we noted that pursuant to the Class Action Lawsuits Law 5766-2006 and the Regulations enacted thereunder, at the current stage of the court proceedings with respect to the 2015 Motion such shareholder cannot petition to be excluded from the Purported Class. The court ordered the shareholder to respond to our response and he has done so. In May 2018, the shareholder filed an independent lawsuit against us in the Haifa Magistrates Court seeking damages of approximately NIS 1.1 million (approximately $306,000) (the "Separate Lawsuit"). In August 2018, the Haifa Magistrates Court transferred the Separate Lawsuit to the Tel Aviv Magistrates Court. We are of the view that such shareholder's claims are identical to the asserted claims for damages in the 2015 Motion, and we notified the court of such and sought a stay of proceedings pending the outcome of the 2015 Motion. A preliminary hearing on our motion to dismiss the Separate Lawsuit and/or stay the proceedings was held in May 2019, at which the court dismissed the claim without prejudice. This shareholder subsequently filed a new separate claim against the Company in the Haifa District Court – Economic Division, which was transferred to the Tel Aviv District Court – Economic Division. In January 2020, the Tel Aviv District Court – Economic Division accepted the Company's position that the shareholder's claims are identical to the asserted claims for damages in the 2015 Motion, and entered a stay of proceedings pending the outcome of the 2015 Motion.

We have been advised by our attorneys that the likelihood of us not incurring any financial obligation as a result of the 2015 Motion and the Separate Lawsuit exceeds the likelihood that we will incur a financial obligation. At this stage however, we are unable, with any degree of certainty, to make any other evaluations or any other assessments with respect to the 2015 Motion's and/or the Separate Lawsuit's probability of success or the scope of potential exposure, if any.

ISA Investigation

In Israel, we were previously subject to a formal investigation by the Israeli Securities Authority (respectively, the "ISA Investigation" and the "ISA") into our public disclosures around certain aspects of the studies related to its therapeutic candidate, Consensi. On August 13, 2019, the Administrative Enforcement Committee (the "Committee") of the ISA approved an administrative enforcement agreement, titled Enforcement Arrangement ("Enforcement Arrangement"), entered into by and amongst the ISA, the Company, Isaac Israel, our chief executive officer, Dr. Paul Waymack, our former chairman, and Simcha Rock, our former chief financial officer and currently a director, pursuant to which the Company and each of Messrs. Israel, Waymack and Rock settled the ISA's claims that under Israeli Securities Laws the Company made negligent disclosures in a number of its historical reports filed with the ISA in 2014 and 2015, and the ISA decided to discontinue its criminal investigation and to cease all proceedings us and our principals.

As part of the Enforcement Arrangement, the Company agreed to pay a fine of NIS 1,500,000 (approximately $430,000), payable in 24 consecutive monthly payments, of which $322,500 has been paid to date, and the different principals agreed to each pay a fine. Messrs. Israel and Rock each also agreed to be subject to a conditional prohibition to serve as a senior officer in a supervised body under the Israeli Securities Law for a period of 12 months, in the event that he violates certain sections under the Israeli securities laws within two years.

The above is a summary of the material terms of the Enforcement Arrangement. An English translation copy of the Enforcement Arrangement is attached as an exhibit to this Annual Report on Form 20-F. The Enforcement Arrangement has been attached as an exhibit to this Annual Report on Form 20-F to provide you with information regarding its terms. The summary above of the material terms of the Enforcement Arrangement is qualified in its entirety by reference to the Enforcement Arrangement. This summary may not contain all of the information about the Enforcement Arrangement that is important to you. We urge you to read the Enforcement Agreement carefully. The full binding Hebrew text of the Enforcement Arrangement and the Committee ruling were published by the ISA on its Administrative Enforcement Arrangements webpage.

2017 Motions to Approve a Class Action in Israel

On February 16, 2017, we announced that four lawsuits and motions to approve the lawsuits as a class action lawsuit were filed against us and certain of our office holders in the Tel Aviv District Court (Economic Division), and served on us, with each such motion relating to the ISA Investigation into our public disclosures around certain aspects of the studies related to our lead drug candidate, Consensi (the "2017 Motions"). One of these motions was subsequently withdrawn.

The petitioners in one of the motions petitioned the court to dismiss the other 2017 Motions ("Petition for Dismissal"). On December 19, 2017, the court granted the Petition for Dismissal and dismissed the other outstanding 2017 Motions.

The remaining motion from the 2017 Motions (the "Surviving Motion") was filed against us, our executive directors and certain of our present and former directors, by certain shareholders who are requesting to act as representatives of all shareholders of record from December 10, 2015 until February 6, 2017. The plaintiffs allege, among other things, that we included misleading information in our public filings which caused the class for which the plaintiffs are seeking recognition, an aggregate loss of approximately NIS 29 million (approximately $9.0 million). The court ordered a stay of proceedings due to the then-ongoing ISA Investigation. Following approval of the Enforcement Arrangement in connection with the ISA Investigation (see above), the stay was lifted. On May 29, 2020 the petitioners in the Surviving Motion filed an amended lawsuit and motion to approve the lawsuit as a class action. On November 15, 2020 the respondents filed their responses to the amended motion to approve the lawsuit as a class action. After filling such responses, the court suggested that both parties' resort to mediation, without admitting or accepting the other party's claim. Both parties accepted such suggestion. We expect that the mediation will be commenced shortly.

Our management rejects the claims in the Surviving Motion. At this preliminary stage we are unable, with any degree of certainty, to make any evaluations or any assessments with respect to the Surviving Motion as to the probability of success or the scope of potential exposure, if any, including, without limitation, the effects of the Enforcement Arrangement and/or the Settlement of the U.S. Class actions (see below) may have on the Surviving Motion.

U.S. Class Actions

In February 2017, class actions lawsuits largely relating to the same matters were filed in the State of California and in the United States District Court for the Southern District of New York against us, our CEO and former CFO, and in the California lawsuits, against the underwriters of our November 2015 initial public offering in the U.S.A. We finalized a settlement agreement with respect to the class actions lawsuits which were filed in the State of California and in the U.S. federal courts against us, our CEO and former CFO, and in the California lawsuits, against the underwriters of our November 2015 initial public offering in the United States, which was approved by the court on March 22, 2019. Under the terms of the settlement, the classes in all of the actions will receive aggregate consideration of $2.0 million (the "US Settlement"). The US Settlement consideration, as well as ancillary expenses, were funded by our insurance carriers. The US Settlement contains no admission of wrongdoing and reiterates that we have always maintained and continue to believe that we did not engage in any wrongdoing or otherwise commit any violation of federal or state securities laws or other laws, including, without limitation, vigorous denials that our public statements were misleading; that we failed to disclose any material information from investors; that we acted in any deceitful manner; that any investment losses sustained by the classes were caused by our or other defendants' alleged misconduct, and that they have any liability to the classes in these actions. The US Settlement also reiterates that our counsel also has researched the applicable law and believes that we and other defendants can successfully defend against all claims in the actions, and that they continue to believe that the claims asserted in the actions have no merit, and the classes have no evidence to support their claims.

Although we maintain directors' and officers' liability insurance, with an extension to cover the Company as well, and which is expected to cover much of our expected costs (legal and otherwise) in connection with the ongoing lawsuits described above after payment by us of the policy deductibles, the insurance companies may reject our claims for coverage under the policy or the coverage may not be adequate to cover future claims. Furthermore, we were required to indemnify our underwriters for their legal defense costs or any other damages in the California lawsuits, and such indemnification was not covered under the policy. We paid our underwriters to indemnify them for their legal costs in connection with the California lawsuits an aggregate amount of approximately $186,900.

On December 21, 2020, the University and BIRAD filed a statement of claim to the court against TyrNovo, the Company, its officers and others. In the claim, the petitioners allege that the University is the rightful owner of a patent owned by TyrNovo. The main remedy sought by the petitioners is a declaratory relief under which the University is declared the owner of such patent. We plan to file our response in April 2021, when it is due. At this preliminary stage we are unable, with any degree of certainty, to make any evaluations or any assessments with respect to the probability of success or the scope of potential exposure, if any.

On August 4, 2020, Lupin notified Purple and Coeptis, our distribution partner for Consensi, that it had filed an abbreviated NDA with the FDA to market a generic version of Consensi. Lupin also sent both parties a Paragraph IV Notice Letter alleging that certain of our patents are invalid and/or not infringed by Lupin's proposed generic product. In September 2020, we filed a complaint in the United States District Court for the District of New Jersey against Lupin and claimed that Lupin's proposed generic product infringes certain of our patents and sought declaratory and injunctive relief. On January 12, 2021, the court issued an order providing a schedule for the briefs and other items to be submitted, and the discovery to be conducted, by the parties, which will take place over the course of 2021.

Other than as described above, we are not currently a party to any significant legal or arbitration proceedings involving any third party, including governmental proceedings, pending or known to be contemplated, which may have, or have had in the recent past, significant effects on the Company's financial position or profitability.

Dividend Policy

We anticipate that, for the foreseeable future, we will retain any future earnings to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends for at least the next several years. We did not declare dividends during the three most recent fiscal years.

The distribution of dividends may also be limited by the Companies Law, which permits the distribution of dividends only out of retained earnings or earnings derived over the two most recent fiscal years, whichever is higher, provided that there is no reasonable concern that payment of a dividend will prevent a company from satisfying its existing and foreseeable obligations as they become due. Our amended and restated articles of association provide that dividends will be paid at the discretion of, and upon resolution by, our board of directors, subject to the provision of the Companies Law.

B. Significant Changes

Except as otherwise disclosed in this Annual Report on Form 20-F, no significant change has occurred since December 31, 2020.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ordinary shares are currently traded on the TASE under the symbol "PPBT". Our ADSs are currently traded on NASDAQ under the symbol "PPBT". Our Series A warrants to purchase ADSs were traded on NASDAQ under the symbol "KTOVW" until November 23, 2020. The Series A warrants expired on November 25, 2020.

B. Plan of Distribution

Not applicable.

C. Markets

See "—Offer and Listing Details" above.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

A copy of our memorandum of association and amended and restated articles of association are attached as Exhibit 1.1 and Exhibit 1.2 to this Annual Report, respectively. 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.

Securities Registers

Our registration company for our shares is Registration Company of United Mizrahi Bank Ltd, and its address is 7 Jabotinsky St., Ramat Gan, Israel.

Our transfer agent and registrar for our ADSs is the depositary for our ADRs, The Bank of New York Mellon, and its address is 101 Barclay Street, New York, NY.

Objects and Purposes

According to our memorandum of association and our amended and restated articles of association, we are permitted to engage in any legal business. Our registration number with the Israeli Registrar of Companies is Public Company number 520031238.

Shareholder Meetings

Under regulations promulgated under the Companies Law, we are required to publish notices at least 21 days prior to a shareholders' meeting. However, we are required to publish notices at least 35 calendar days prior to any shareholders' meeting in which the agenda includes matters which may be voted on by voting instruments. Regulations under the Companies Law exempt companies whose shares are listed for trading both on a stock exchange in and outside of Israel, from some provisions of the Companies Law. These regulations exempt us from some of the requirements of the Israeli proxy regulations, under certain circumstances.

According to the Companies Law and the regulations promulgated thereunder, as applicable to Purple Biotech, for purposes of determining the shareholders entitled to notice and to vote at such meeting, the board of directors may fix the record date not more than 40 nor less than four calendar days prior to the date of the meeting, provided that an announcement regarding the general meeting shall be given prior to the record date.

Holders of ordinary shares are entitled to one vote for each ordinary share held on all matters submitted to a vote of shareholders. Pursuant to our articles of association, the quorum required for an ordinary meeting of shareholders consists of at least two shareholders present, in person or by proxy, or who has sent us a voting instrument indicating the way in which he or she is voting, who hold or represent, in the aggregate, at least 25% of the voting rights of our outstanding share capital. A meeting adjourned for lack of a quorum is adjourned to the same day in the following week at the same time and place or any time and place as prescribed by the board of directors in notice to the shareholders. At the reconvened meeting one shareholder at least, present in person or by proxy constitutes a quorum except where such meeting was called at the demand of shareholders. With the agreement of a meeting at which a quorum is present, the chairman may, and on the demand of the meeting he must, adjourn the meeting from time to time and from place to place, as the meeting resolves.

Under Israeli law, annual general meetings of our shareholders are to be held once every year within a period of not more than 15 months after the last preceding annual general shareholders' meeting. Our board of directors may call special general meetings of shareholders. The Companies Law provides that a special general meeting of shareholders may be called by the board of directors or by a request of two directors or 25% of the directors in office, whichever is the lower, or by shareholders holding at least 5% of our issued share capital and at least 1% of the voting rights, or of shareholders holding at least 5% of our voting rights, subject to the provisions set forth in our amended and restated articles of association.

Our ADS holders may instruct the depositary how to vote the number of deposited ordinary shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of Israel and the provisions of our amended and restated articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary as described above, you will not be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed by the holder of the ADSs or as described in the following sentence. If we asked the depositary to solicit your instructions at least 30 days before the meeting date but the depositary does not receive voting instructions from you by the specified date, it will consider you to have authorized and directed it to give a discretionary proxy to a person designated by us to vote the number of deposited securities represented by your ADSs. The depositary will give a discretionary proxy in those circumstances to vote on all questions at to be voted upon unless we notify the depositary that:

- we do not wish to receive a discretionary proxy;
- there is substantial shareholder opposition to the particular question; or
- the particular question would have an adverse impact on our shareholders.

We are required to notify the depositary if one of the conditions specified above exists.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

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.

For information regarding the approval of director compensation and interested party transactions and the rights of directors to vote on transactions in which they have a personal interest under Israeli law, see "Item 6. Directors, Senior Management and Employees - C. Board Practices – "Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law."

Exclusive Forum for Shareholder Litigation

Our amended and restated articles of association provide that, unless we consent in writing to the selection of an alternative forum, the Tel Aviv District Court (Economic Division in the State of Israel (or, if the Tel Aviv District Court does not have jurisdiction, and no other Israeli court has jurisdiction, the federal district court for the District of New York) shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our shareholders, and (3) any action asserting a claim arising pursuant to any provision of the Companies Law or the Israeli Securities Law 5728-1968, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. In addition, unless we consent in writing to the selection of an alternative forum, and other than with respect to plaintiffs or a class of plaintiffs which may be entitled to assert claims in the courts of the State of Israel with respect to any causes of action arising under the Securities Act of 1933, the federal district courts of the United States for the District of New York shall be the exclusive forum for any complaint asserting a cause of action arising under the Securities Act of 1933. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to these provisions. This forum selection provision will limit shareholders' choice in selecting a judicial forum for disputes with us that it finds favorable or convenient and may have the effect of discouraging lawsuits against us or our directors and officers.

C. Material Contracts

FameWave Acquisition

The following is a summary of the material terms of the FameWave Stock Purchase Agreement dated March 14, 2019 (the "Acquisition Agreement"). A copy of the Acquisition Agreement, including ancillary agreements which were entered into in connection with the transactions contemplated by the Acquisition Agreement, are attached as exhibits to this Annual Report on Form 20-F. The summary of the material terms of the Acquisition Agreement (including any of its ancillary agreements) below and elsewhere in this Annual Report on Form 20-F is qualified in its entirety by reference to the Acquisition Agreement and/or the applicable ancillary agreement. This summary may not contain all of the information about the Acquisition Agreement and/or any applicable ancillary that is important to you. We urge you to read carefully the Acquisition Agreement (including any of its ancillary agreements) in its entirety as these are the legal documents governing the transactions.

Acquisition Agreement

Upon the terms and subject to the conditions of the Acquisition Agreement, in January 2020, we acquired 100% of the issued and outstanding shareholdings from the shareholders of FameWave, in exchange for the issuance of our ADSs and Kitov Warrants, and FameWave became a wholly-owned subsidiary of the Company. In addition, we provided a loan to FameWave to pay cCAM, a wholly owned subsidiary of MSD for the return of the intellectual property rights to CM24 to FameWave and to repay certain loans provided by FameWave's shareholders to FameWave to conduct business pursuant to the approved business budget. As part of the Acquisition Agreement, three leading life science focused investment funds, Orbimed Israel Partners, Pontifax, and Arkin Holdings, who collectively held approximately 90% of FameWave, concurrently invested $3.5 million in us at closing in exchange for additional newly issued ADSs of the Company, priced at $12.30 per ADS, in a private placement.

In consideration of the transfer of the FameWave shares to us and the other obligations set forth in the Acquisition Agreement, the aggregate purchase price paid by us for 100% of FameWave shares consisted of the issuance by us to the FameWave Shareholders, and, on behalf of FameWave, to (i) THM, and (ii) the lenders with outstanding balances under the certain Convertible Loan Agreement dated February 13, 2018, their respective share, as set forth in the allocation table provided to us prior to closing of the transaction, of (a) 807,561 of our ADSs (equal to $9,933,000 divided by $12.30), and such ADSs with aggregate value of $9,933,000 served as the total consideration for 100% of the fully diluted share capital of FameWave, and was allocated among all selling FameWave shareholders, lenders under the Convertible Loan Agreement, THM, and any other persons with equity based rights in FameWave and/or rights to receive consideration from an exit transaction of FameWave or any other type of FameWave reorganization, and (b) Warrants to purchase 403,780 additional ADSs, with an exercise price equal to $19.80 per ADS of Purple Biotech, and with a term of exercise of four years beginning on the date of issuance, and subject to other terms and conditions as set forth herein and in the warrant agreements, the form of which is attached to the Acquisition Agreement.

Each party has agreed to indemnify and hold harmless the other party, such party's respective affiliates, and their respective equity holders, officers, directors, managers, employees, attorneys, accountants, consultants, financial advisors and other agents for penalties, fines, costs, liabilities, obligations, losses, expenses and fees, including court costs and reasonable attorneys' fees and expenses arising out of or resulting from a breach of any representation or warranty or the failure to duly perform or observe any covenant or agreement in the Acquisition Agreement required to be performed or observed before or after the closing date under the Acquisition Agreement.

Ancillary Agreements Related to The Transactions

Lock-Up Agreements

Our ADSs and ADSs issuable upon exercise of the warrants that we issued to the investment funds and other selling shareholders of FameWave who signed the Registration Rights Agreement (as defined below), and the ADSs issued to the investment funds in return for their $3.5 million investment are subject to a lock-up agreement entered into at closing of the transaction restricting transfer or sales for a 12-month period commencing on the date of issuance by us; provided, however, that during the period following 6 months after the date of issuance of the securities and until the end of the such 12-month period, the holder will be allowed to sell the ADS and/or the ADSs issued upon any exercise of the warrants, subject to any statutory resale restrictions or limitations, but only if (i) we have not publicly announced clinical data related to FameWave's products, and (ii) the market price for our ADSs on NASDAQ at the close of the preceding trading day was above $30.00 per ADS.

Registration Rights

At the closing of the transactions contemplated by the Acquisition Agreement, and in order to induce certain FameWave shareholders to sell their FameWave shares to us and/or invest in our ADSs, we entered into, at the closing of the acquisition, a Registration Rights Agreement (the "Registration Rights Agreement") providing for the filing of a registration statement (the "Registration Statement") with the SEC registering for resale of such shareholders' ADSs and ADSs underlying the warrants. Pursuant to the Registration Rights Agreement, we were obligated to file a resale registration statement providing for the resale by such shareholders of their registrable securities by no later than 120 days prior to the end of the above-mentioned lockup period and cause the Registration Statement to be declared effective no later than the end of such lock-up period. We filed such registration statement on Form F-3 on May 13, 2020 (File No. 333-238229) and it was declared effective on May 20, 2020. We undertook to use commercially reasonable efforts to cause the resale registration statement to remain continuously effective for at least 12 months (or such shorter period as will terminate when all of our securities covered by the Registration Statement have been sold or withdrawn).

Voting and Shareholder Undertakings

Each of the investment funds and the other FameWave shareholders party to the Registration Rights Agreement signed a Shareholder's Undertaking in connection with our securities held by them containing, amongst other matters, an undertaking that during the above mentioned lock-up period, and, subsequent to such lock up period until the earlier of: (a) for so long as the aggregate number of our ordinary share equivalents beneficially owned by the shareholder and its group members, as a group, is greater than or equal to 2.5% of our then issued and outstanding ordinary shares or (b) 24 months following the date of the undertaking, the shareholder shall cause all of our voting securities beneficially owned by it or any of its group members or over which it or any of its group members has voting control not to be voted, (i) against all those persons nominated and recommended to serve as directors of the Company by our board of directors and/or any applicable committee thereof and (ii) with respect to any other action, proposal or matter to be voted on by our shareholders, in a manner inconsistent with the recommendation of our board of directors or any applicable committee thereof; provided, however, that the undertakings in sub-clauses (ii) and (ii) above shall not apply to: (1) matters under Sections 270(1), 270(2), 270(3) and 270(4) the Companies Law and matters which require the declaration by officers or shareholders of a personal interest and/or affiliation with a controlling shareholder as defined in, and in accordance with, the Companies Law, or (2) matters directly affecting the development of the technology controlled by FameWave or (3) where, based on a legal advice opinion received in writing by the shareholder, the shareholder reasonably believes that such vote by the shareholder may impose any liability on the shareholder.

In addition, during a standstill period until the earlier of: (i) for so long as the aggregate number of our ordinary share equivalents beneficially owned by the shareholder and its group members, as a group, is greater than or equal to 2.5% of our then issued and outstanding ordinary shares or (ii) 24 months following the date of the undertaking, and subject to certain exceptions set forth in the undertaking, the shareholder shall not, directly or indirectly, and shall cause its representatives (to the extent acting on behalf of the shareholder) or any of its group members or over which it or any of its group members has voting control not to, directly or indirectly, to, without the prior written consent of, or waiver by, us (all defined terms below are as in the Shareholder's Undertaking filed as an Exhibit to this Annual Report):

- acquire, offer or seek to acquire, agree to acquire or make a proposal (including any private proposal to the Company or the Board) to acquire, by purchase or otherwise (including through the acquisition of Beneficial Ownership), any securities (including any Equity Securities or Voting Securities) or Derivative Instruments, or direct or indirect rights to acquire any securities (including any Equity Securities or Voting Securities) or Derivative Instruments, of the Company or any Subsidiary or Affiliate of the Company or any successor to or Person in Control of the Company, or any securities (including any Equity Securities or Voting Securities) or indebtedness convertible into or exchangeable for any such securities or indebtedness; provided that the Shareholder may acquire, offer or seek to acquire, agree to acquire or make a proposal to acquire Ordinary Share Equivalents (and any securities (including any Equity Securities or Voting Securities) convertible into or exchangeable for Ordinary Share Equivalents) and Derivative Instruments with respect to Ordinary Share Equivalents, if, immediately following such acquisition, the collective Beneficial Ownership of Ordinary Share Equivalents of the Shareholder and its Group Members, as a group, would not exceed the Standstill Level;

- offer, or seek to acquire, or participate in any acquisition of a majority of the consolidated assets of the Company and its Subsidiaries, taken as a whole;

- conduct, fund or otherwise become a participant in any "tender offer" (as such term is used in Regulation 14D under the Exchange Act or Chapters Two and Three of Part VIII the Companies Law) or in any merger or merger type transaction, involving Equity Securities, Voting Securities or any securities convertible into, or exercisable or exchangeable for, Equity Securities or Voting Securities, in each case either not approved by the Board or where the representative of the Incumbent Directors has informed the Shareholder in writing that such offer or transaction was approved by the Board when a majority of directors at the time of such approval or recommendation are not Incumbent Directors;

- otherwise act in concert with others to seek to control or influence the Board or shareholders of the Company or its Subsidiaries or Affiliates; provided that nothing in this clause (d) shall preclude the Shareholder or its Representatives from engaging in discussions with the Company or its Representatives;

- make or join or become a participant (as defined in Instruction 3 to Item 4 of Schedule 14A under the Exchange Act) in (or in any way knowingly encourage) any "solicitation" of "proxies" (as such terms are defined in Regulation 14A as promulgated by the SEC and assuming for this purpose that the Company was subject to the proxy rules under Section 14 of the Exchange Act) (including, in each case, similar concepts under Israeli law, including submission of positions statements), or consent to vote any Voting Securities or any of the voting securities of any Subsidiaries or Affiliates of the Company (including through action by written consent), or otherwise knowingly advise or influence any Person with respect to the voting of any securities of the Company or its Subsidiaries or Affiliates;

- make any public announcement with respect to, or solicit or submit a proposal for, or offer, seek, propose or indicate an interest in (with or without conditions) any merger or merger type transaction, including, but not limited to, a merger pursuant to Chapter One of Part VIII or Chapter Three of Part IX of the Companies Law, consolidation, business combination, "tender offer" (as such term is used in Regulation 14D under the Exchange Act or Chapters Two and Three of Part VIII of the Companies Law), recapitalization, reorganization, purchase or license of a material portion of the assets, properties, securities or indebtedness of the Company or any Subsidiary or Affiliate of the Company, or other similar extraordinary transaction involving the Company, any Subsidiary of the Company or any of its securities or indebtedness, or enter into any discussions, negotiations, arrangements, understandings or agreements (whether written or oral) with any other Person regarding any of the foregoing;

- call or seek to call a meeting of shareholders of the Company or initiate any shareholder proposal or meeting agenda item for action of the Company's shareholders, or seek election or appointment to or to place a representative on the Board or seek the removal of any director from the Board;

- form, join, become a member or in any way participate in a Group (other than with the Shareholder, any of its Group Members or any counterparty in connection with a Hedging Arrangement with respect to the securities of the Company or any of its Subsidiaries or Affiliates;

- deposit any Voting Securities in a voting trust or similar Contract or subject any Voting Securities to any voting agreement, pooling arrangement or similar arrangement or Contract, or grant any proxy with respect to any Voting Securities;

- make any proposal or disclose any plan, or cause or authorize any of its and their directors, officers, employees, agents, advisors and other Representatives to make any proposal or disclose any plan on its or their behalf, inconsistent with the foregoing restrictions;

- knowingly take any action or cause or authorize any of its and their directors, officers, employees, agents, advisors and other Representatives to take any action on its or their behalf, that would reasonably be expected to require the Company or any of its Subsidiaries or Affiliates to publicly disclose any of the foregoing actions or the possibility of a business combination, merger or other type of transaction or matter described;

- knowingly advise, assist, arrange or otherwise enter into any discussions or arrangements with any third party with respect to any of the foregoing; or

- directly or indirectly, contest the validity of, any provision of these provisions of the Acquisition Agreement.

Product Manufacturing Agreement with Dexcel

In November 2018, we entered into the Product Manufacturing Agreement, as amended on May 17, 2020, with Dexcel, a global pharmaceutical company, which has been involved in the manufacture and marketing of more than 55 branded and generic products. Pursuant to the Product Manufacturing Agreement, Dexcel manufactured scale-up batches as well as validation batches of Consensi in anticipation of the launch of the drug in the U.S. by our U.S. distribution partner. The agreement also provides for an ongoing supply of Consensi to our distribution partners. Dexcel previously manufactured Consensi for us under a Development Services Agreement, pursuant to which Dexcel developed the formulation for Consensi, conducted the subsequent stability testing and manufacturing scale-up in quantities adequate for submission of the NDA to the FDA.

Dexcel manufactures Consensi in three dosage forms. We provide Dexcel with packaging and labeling instructions, 12-month rolling forecasts, and purchase orders. The Manufacturing Agreement contains various representations, warranties, indemnity, and intellectual property provisions, common to agreements of such nature. Pursuant to the Manufacturing Agreement we also entered into a Quality Agreement with Dexcel and Coeptis.

According to the previous Development Services Agreement with Dexcel, as well as the recent Manufacturing Agreement with Dexcel, any new intellectual property rights resulting from the development made by Dexcel which are applicable to manufacture, research, development, making of, use, sale, production commercialization and distribution of Consensi shall be jointly and equally owned (50%/50%) by Dexcel and us. We filed a patent application, in partnership with Dexcel, which is related to pharmaceutical formulations of celecoxib and amlodipine and methods of preparing the same and were granted this patent in the U.S. in March 2021. Under the Development Services Agreement and Manufacturing Agreement, each of Dexcel and we granted the other party a fully-paid, non-exclusive, perpetual world-wide license to the jointly and equally owned new intellectual property rights. Accordingly, we expect that there will be no royalty payments due to Dexcel for our use of this jointly and equally owned new intellectual property rights.

Commercialization Agreement for United States

In early January 2019, we entered into an exclusive marketing and distribution agreement with Coeptis for the commercialization of Consensi in the U.S. market. The agreement provides for total milestone payments from Coeptis of $3.5 million, of which we received the initial $1 million milestone concurrent with finalization of the agreement, a $1.5 reimbursement payment upon completion of an agreed CMC plan. In addition, the agreement entitled us to 60% of Coeptis' net profit on Consensi sales until such time as we have received $13 million in such profit distributions, following which we would then be entitled to 40% of Coeptis' net profit on all subsequent Consensi sales. In October 2019, we amended the agreement with Coeptis. Under the terms of the amended agreement, we will receive 20% in royalties on net sales of Consensi with minimum royalties of $4.5M over 3 years. In addition, we are entitled to receive up to $99.5 million in milestone and reimbursement payments, of which $3.5 million was already received and $96 million is subject to certain pre-defined commercial milestones. The agreement is for a term of fifteen years and may be extended for additional two-year terms, and includes customary provisions, as well as certain residual rights and obligations of the parties following termination. As of the date of this Annual Report on Form 20-F, Coeptis has not fulfilled all of its obligations as per the agreement.

Rentschler Biopharma Manufacturing Agreement

We have entered into a master development services agreement with Rentschler in Germany, pursuant to which Rentschler shall manufacture CM24 batches for clinical studies for a total amount of $6.4 million over a period of two years. Rentschler manufactured and provided the initial batch, and it is expected to manufacture the second (and final) batch in the near future. The manufacturing agreement contains various customary representations, warranties, indemnity, and intellectual property provisions. Pursuant to the Manufacturing Agreement, we entered into a Quality Agreement with Rentschler.

Other Agreements

For a description of other agreements, please see "Item 3. Key Information – D. Risk Factors – Risks Related to Our Business and Regulatory Matters", "Item 4. Information on the Company – B. Business Overview – Consensi – "License Agreement for Territory of South Korea," "Commercialization Agreement for China" and "Commercialization Agreement for the United States", "Item 4. Information on the Company – B. Business Overview – Intellectual Property", "Item 4. Information on the Company- B. Business Overview - Intellectual Property –License Agreement with Tel HaShomer", "Item 4. Information on the Company- B. Business Overview - Intellectual Property –Exclusive License Agreement with Yissum."

For information on exemption and indemnification letters granted to our officers and directors, please see "Item 6 – Directors, Senior Management and Employees – C. Board Practices – Exemption, Insurance and Indemnification of Directors and Officers."

The above summary of certain terms and provisions of our material and other agreements is not necessarily complete and is subject to, and is qualified in its entirety by the provisions of any copies of any agreements which are filed as an exhibit to this Annual Report on Form 20-F. You should carefully review the terms and provisions set forth in the agreements attached as exhibits. The agreements exhibited to this Annual Report on Form 20-F have been attached as exhibits to this report to provide investors and security holders with information regarding its terms. It is not intended to provide any factual information about us or any counterparties to such agreements. Any of our representations, warrants, covenants, disclosures or other matters set forth in such agreements are for the benefit of the counterparties of such agreements only, and not for the benefit of any third parties, including any of our securities holders.

D. Exchange Controls

There are currently no material Israeli currency control restrictions on payments of dividends or other distributions with respect to our securities or the proceeds from the sale of our securities, except under certain circumstances, for shareholders who are subjects of countries that are, or have been, in a state of war with Israel. However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time. Israeli residents have an obligation to file reports with the Bank of Israel regarding certain transactions.

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 and ADSs. 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 summary of the material Israeli tax laws applicable to us, and some Israeli Government programs benefiting us. This section also contains a discussion of some Israeli tax consequences to persons owning our ordinary shares and ADSs. This summary does not discuss all the 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 subject to special treatment under Israeli law. Examples of this kind of investor include traders in securities or persons that own, directly or indirectly, 10% or more of our outstanding voting capital, all of whom are subject to special tax regimes not covered in this discussion. Some parts of this discussion are based on a new tax legislation which has not been subject to judicial or administrative interpretation. The discussion below is subject to change, including due to amendments under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which change could affect the tax consequences described below. The discussion should not be construed as legal or professional tax advice and does not cover all possible tax considerations.

Shareholders 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 and ADSs, including, in particular, the effect of any foreign, state or local taxes.

General Corporate Tax Structure in Israel

The Israeli corporate tax rate applicable to Israeli resident companies is 23%.

Taxation of Shareholders

Capital Gains

Capital gain tax is imposed on the disposal of capital assets by an Israeli resident and on the disposal of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel, unless an exemption is available or unless an applicable double tax treaty between Israel and the seller's country of residence provides otherwise. The Israeli Income Tax Ordinance distinguishes between "Real Gain" and the "Inflationary Surplus." Real Gain is the excess of the total capital gain over Inflationary Surplus computed generally on the basis of the increase in the Israeli Consumer Price Index between the date of purchase and the date of disposal. Inflationary Surplus is not subject to tax.

Real Capital Gain accrued by individuals on the sale of the Ordinary Shares or ADSs will be taxed at the rate of 25%. However, if the individual shareholder is a "Controlling Shareholder" (*i.e*., a person who holds, directly or indirectly, alone or together with another, 10% or more of one of the Israeli resident company's means of control) 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%.

Corporate and individual shareholders dealing in securities in Israel are taxed at the tax rates applicable to business income which is 23% for corporations, and a marginal tax rate of up to 47% for individuals.

Notwithstanding the foregoing, real capital gains generated from the sale of our Ordinary Shares or ADSs by a non-Israeli shareholder may be exempt from Israeli tax under the Israeli Income Tax Ordinance provided that the following cumulative conditions are met: (i) the Ordinary Shares or ADSs were purchased upon or after the registration of the Ordinary Shares or ADSs on the stock exchange and (this condition will not apply to shares purchased on or after January 1, 2009); and (ii) the seller does not have a permanent establishment in Israel to which the generated capital gain is attributed. However, non-Israeli resident corporations will not be entitled to the foregoing exemption if Israeli residents: (i) hold more than 25% or more means of control in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the income or profits of such non-Israeli corporation, whether directly or indirectly. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the Ordinary Shares or ADSs are deemed to be business income.

In addition, the sale of the Ordinary Shares or ADSs may be exempt from Israeli capital gain tax under the provisions of an applicable double tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for such an exemption). For example, the Convention between the Government of the U.S. and the Government of the State of Israel with respect to Taxes on Income (the "U.S.- Israel Double Tax Treaty") exempts a U.S. resident (for purposes of the treaty) from Israeli capital gains tax in connection with the sale of the Ordinary Shares or ADSs, provided that: (i) the U.S. resident owned, directly or indirectly, less than 10% of the voting power of the company at any time within the 12 month period preceding such sale; (ii) the U.S. resident, being an individual, is present in Israel for a period or periods of less than 183 days in the aggregate during the taxable year; (iii) the capital gain from the sale, exchange or disposition was not derived through a permanent establishment of the U.S. resident; and (iv) the capital gains arising from such sale, exchange or disposition is not attributed to real estate located in Israel or a resident in Israel; however, under the U.S-Israel Double Tax Treaty, the taxpayer would be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange or disposition, subject to the limitations under U.S. law applicable to foreign tax credits. The U.S-Israel Double Tax Treaty does not relate to U.S. state or local taxes.

Payers of consideration for the Ordinary Shares or ADSs, including the purchaser, the Israeli stockbroker or the financial institution through which the Ordinary Shares or ADSs are held, are obligated, subject to certain exemptions, to withhold tax upon sale of Ordinary Shares or ADSs from the amount of consideration paid upon the sale of the securities (or on the Real Capital Gain realized on the sale, if known), at a rate of 25% for an individual or at a rate of corporate tax for a corporation (23% in 2019 and thereafter).

Upon the sale of traded securities, a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid to the Israel Tax Authority on January 31 and July 31 of every tax year in respect of sales of traded securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Israeli Income Tax Ordinance and regulations promulgated thereunder, such return need not be filed and no advance payment must be paid. Capital gains are also reportable on annual income tax returns.

Dividends

Dividends distributed by a company from income, which is not attributed to an Approved Enterprise, a Benefited Enterprise or a Preferred Enterprise as defined in the Israel's Encouragement of Capital Investment Law, 1959, to a shareholder who is an Israeli resident individual will be generally subject to income tax at a rate of 25%. However, a 30% tax rate will generally apply if the dividend recipient is a Controlling Shareholder, as defined above, at the time of distribution or at any time during the preceding 12-month period. If the recipient of the dividend is an Israeli resident corporation, such dividend will generally not be subject to tax provided that the income from which such dividend is distributed, derived or accrued within Israel. A distribution of dividend by a company from income attributed to a Preferred Enterprise will generally be subject to withholding tax in Israel at the following tax rates: Israeli resident individuals - 20% with respect to dividends distributed as of 2014, or such lower rate as may be provided in an applicable tax treaty; and Israeli resident companies - 0%. Dividends distributed from income attributed to an Approved Enterprise and/or a Benefited Enterprise are subject to a tax rate of 15%. If the dividend is attributable partly to income derived from an Approved Enterprise, Benefited Enterprise or Preferred Enterprise, and partly from other sources of income, the income tax rate will be a blended rate reflecting the relative portions of the types of income.

Non-Israeli residents (either an individual or a corporation) are generally subject to Israeli tax on the receipt of dividends at the rate of 25% (30% if the dividend recipient is a Controlling Shareholder at the time of distribution or at any time during the preceding 12-month period). Dividends distributed by an Israeli resident company from income, which is attributed to a Preferred Enterprise, to a non-Israeli resident (either an individual or a corporation) are generally subject to withholding tax at a rate of 20%. These rates may be reduced under the provisions of an applicable double tax treaty. For example, under the U.S.-Israel Double Tax Treaty, the following tax rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting stock of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain types of interest or dividends the tax rate is 12.5%; (ii) if both the conditions mentioned in clause (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate under The Law for the Encouragement of Capital Investments, 1959, the tax rate is 15%; and (iii) in all other cases, the tax rate is 25%. The aforementioned rates under the U.S.-Israel Double Tax Treaty will not apply if the dividend income is attributed to a permanent establishment of the U.S. resident in Israel.

A non-Israeli resident who receives dividend income derived from or accrued from Israel, from which the full amount of tax was withheld at source, is generally exempt from the obligation to file tax returns in Israel with respect to such income, provided that (i) such income was not generated from business conducted in Israel by the taxpayer, (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed and (iii) the taxpayer is not obliged to pay Excess Tax (as described below).

Payers of dividends on our shares, including the Israeli stockbroker effectuating the transaction, or the financial institution through which the securities are held, are required, subject to any of the foregoing exemptions, reduced tax rates and the demonstration of a shareholder of his, her or its foreign residency, to withhold taxes upon the distribution of dividends at a rate of 25%, provided that the shares are registered with a nominee company (for corporations and individuals).

Excess Tax

Individual holders who are subject to tax in Israel (whether any such individual is an Israeli resident or non-Israeli resident) and who have taxable income that exceeds a certain threshold in a tax year (NIS 651,600 for 2020 and NIS 647,640 for 2021), linked to the Israeli Consumer Price Index), will be subject to an additional tax at the rate of 3% on his or her taxable income for such tax year that is in excess of such amount. For this purpose, taxable income includes taxable capital gains from the sale of securities and taxable income from interest and dividends, subject to the provisions of an applicable double tax treaty.

Estate and Gift Tax

Israeli law presently does not impose estate or gift taxes.

U.S. Federal Income Tax Considerations

The following is a description of certain U.S. federal income tax consequences relating to the acquisition, ownership and disposition of our ADSs by a holder. This description addresses only the U.S. federal income tax consequences to holders that are initial purchasers of our ADSs and that hold such ADSs as capital assets. This description does not address tax considerations applicable to holders that may be subject to special tax rules, including, without limitation:

- banks, 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 or organizations;
- certain former citizens or residents of the United States;
- persons that received our ADSs as compensation for the performance of services;
- persons that will hold our ADSs 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 ADSs through such an entity;
- U.S. Holders (as defined below) whose "functional currency" is not the U.S. dollar; or
- holders that own directly, indirectly or through attribution 10% or more of the voting power or value of our shares.

Moreover, this description does not address the U.S. federal estate, gift, or alternative minimum tax consequences, or any U.S. state, local or non-U.S. tax consequences of the acquisition, ownership and disposition of our ADSs.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, in each case as in effect and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively and could affect the tax consequences described below. There can be no assurances that the U.S. Internal Revenue Service, or IRS, will not take a different position concerning the tax consequences of the acquisition, ownership and disposition of our ADSs or that such a position would not be sustained. Holders should consult their own tax advisers concerning the U.S. federal, state, local and foreign tax consequences of acquiring, owning and disposing of our ADSs in their particular circumstances.

For purposes of this description, the term "U.S. Holder" means a beneficial owner of our ADSs that, for U.S. federal income tax purposes, is (i) a citizen or resident of the United States, (ii) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax regardless of its source or (iv) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions or (y) that has elected to be treated as a domestic trust for U.S. federal income tax purposes.

A "Non-U.S. Holder" is a beneficial owner of our ADSs that is neither a U.S. Holder nor a partnership (or other entity treated as a partnership for U.S. federal income tax purposes).

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds our ADSs, the U.S. federal income tax consequences relating to an investment in our ADSs will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax consequences of acquiring, owning and disposing of our ADSs in its particular circumstances.

Persons considering an investment in our ADSs should consult their own tax advisors as to the particular tax consequences applicable to them relating to the acquisition, ownership and disposition of our ADSs , including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Exchange of ADSs for Ordinary Shares

In general, if you hold ADSs, you will be treated as the holder of the underlying ordinary shares represented by those ADSs for U.S. federal income tax purposes. Accordingly, gain or loss generally will not be recognized if you exchange ADSs for the underlying ordinary shares represented by those ADSs. In addition, you will receive a basis in your ordinary shares equal to the basis of your ADSs exchanged for such shares.

Taxation of Dividends and Other Distributions on Our ADSs

Subject to the discussion below under "Passive Foreign Investment Company Consequences," if you are a U.S. Holder, the gross amount of any distribution made to you with respect to our ADSs before reduction for any Israeli taxes withheld therefrom, generally will be includible in your income as dividend income to the extent such distribution is paid out of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. Non-corporate U.S. Holders may qualify for the lower rates of taxation with respect to dividends on ADSs applicable to "qualified dividends," provided that certain conditions are met, including certain holding period requirements and the absence of certain risk reduction transactions. Such lower rate of taxation shall not apply if we are a PFIC for the taxable year in which we pay a dividend. Moreover, such dividends will not be eligible for the dividends received deduction generally allowed to corporate U.S. Holders irrespective of PFIC status. 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 your adjusted tax basis in our ADSs and thereafter as either long-term or short-term capital gain depending upon whether the U.S. Holder has held our ADSs for more than one year as of the time such distribution is received.

If you are a U.S. Holder, dividends paid to you with respect to our ADSs will be foreign source income for foreign tax credit purposes. Subject to certain conditions and limitations, Israeli tax withheld on dividends may be deducted from your taxable income or credited against your U.S. federal income tax liability. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends generally constitute "passive category income." A foreign tax credit for foreign taxes imposed on distributions may be denied if you do not satisfy certain minimum holding period requirements. The rules relating to the determination of the foreign tax credit are complex, and you should consult your tax advisor to determine whether and to what extent you will be entitled to this credit.

The amount of a distribution paid to a U.S. Holder in a foreign currency will be the dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the U.S. Holder receives the distribution, regardless of whether the foreign currency is converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. Holder realizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in foreign currency are converted into U.S. dollars on the day they are received, a U.S. Holder generally should not be required to recognize foreign currency gain or loss in respect of the dividend.

Subject to the discussion below under "Backup Withholding Tax and Information Reporting Requirements," if you are a Non-U.S. Holder, you generally will not be subject to U.S. federal income (or withholding) tax on dividends received by you on your ADSs, unless:

- you conduct a trade or business in the U.S. and such income is effectively connected with that trade or business (and, if required by an applicable income tax treaty, the dividends are attributable to a permanent establishment or fixed base that such holder maintains in the U.S.); or

- you are an individual and have been present in the U.S. for 183 days or more in the taxable year of such sale or exchange and certain other conditions are met.

Sale, Exchange or Other Disposition of Our ADSs

Subject to the discussion below under "Passive Foreign Investment Company Consequences," if you are a U.S. Holder, you generally will recognize gain or loss on the sale, exchange or other disposition of our ADSs equal to the difference between the amount realized on such sale, exchange or other disposition and your adjusted tax basis in our ADSs and such gain or loss will be capital gain or loss. The adjusted tax basis in an ADS generally will be initially determined as described above in "Tax Basis of each ADS." If you are a non-corporate U.S. Holder, capital gain from the sale, exchange or other disposition of an ADS is generally eligible for a preferential rate of taxation applicable to capital gains, if your holding period determined at the time of such sale, exchange or other disposition for such ADS exceeds one year (i.e., such gain is long-term capital gain). The deductibility of capital losses is subject to limitations. Any such gain or loss generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes. A foreign tax credit for foreign taxes imposed on capital gains may be denied if you do not satisfy certain minimum holding period requirements. The rules relating to the determination of the foreign tax credit are complex, and it is possible that the ability of a U.S. Holder to claim a foreign tax credit for any such Israeli tax will be limited. You should consult your tax advisor to determine whether, and to what extent, you will be entitled to this credit.

Subject to the discussion below under "Backup Withholding Tax and Information Reporting Requirements," if you are a Non-U.S. Holder, you generally will not be subject to U.S. federal income or withholding tax on any gain realized on the sale or exchange of such ADSs unless:

- such gain is effectively connected with your conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment or fixed base that you maintain in the United States); or

- you are an individual and have been present in the United States for 183 days or more in the taxable year of such sale or exchange and certain other conditions are met.

Passive Foreign Investment Company Consequences

We likely were classified as a Passive Foreign Investment Company (PFIC) for the 2020 tax year. If we are indeed so classified for 2020 or in any other 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 federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of subsidiaries, either:

- at least 75% of its gross income is "passive income"; or

- at least 50% of the average quarterly value of its total gross assets (which may be determined in part by the market value of our ADSs, which is subject to change) 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 includes amounts derived by reason of the temporary investment of funds raised in offerings of our ADSs. 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 receiving directly 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 ADSs, we will generally continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns our ADSs, regardless of whether we continue to meet the tests described above.

If we are indeed properly classified as a PFIC, and you are a U.S. Holder, then unless you make one of the elections described below, a special tax regime will apply to both (a) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for our ADSs) and (b) any gain realized on the sale or other disposition of the ADSs. 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 your 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 such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax, at the U.S. Holder's regular ordinary income rate for the current year and would 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 you 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 ADSs.

If a U.S. Holder makes the mark-to-market election, then, in lieu of being subject to the tax and interest charge rules discussed above, the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of the ADSs at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in its ADSs will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ADSs in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election).

The mark-to-market election is available only if we are a PFIC and our ADSs are "regularly traded" on a "qualified exchange." Our ADSs will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of our ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter. NASDAQ is a qualified exchange for this purpose. Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. Holder may continue to be subject to the tax and interest charge rules discussed above with respect to such holder's indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes, including stock in any of our subsidiaries that are treated as PFICs. If a U.S. Holder makes a mark-to-market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless our ADSs are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

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 section 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.

A U.S. Holder who owns ADSs during any year in which we are a PFIC, will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to us, generally with the U.S. Holder's federal income tax return for that year.

U.S. Holders should consult their tax advisors regarding application of the PFIC rules.

Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may apply to all or a portion of the following items with respect to ADSs: dividend or other distributions, gains from dispositions and "excess distributions" and income from "mark-to-market" elections under the PFIC rules, if applicable. Each U.S. Holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our ADSs.

Backup Withholding Tax and Information Reporting Requirements

U.S. backup withholding tax and information reporting requirements may apply to certain payments to certain holders of our ADSs. Information reporting generally will apply to payments of dividends on our ADSs, and to proceeds from the sale or redemption of our ADSs made within the United States, or by a U.S. payer or U.S. middleman, to a holder of our ADSs, other than an exempt recipient (including a payee that is not a U.S. person that provides an appropriate certification and certain other persons). A payer may be required to withhold backup withholding tax from any payments of dividends on our ADSs, or the proceeds from the sale or redemption of our ADSs within the United States, or by a U.S. payer or U.S. middleman, to a holder, other than an exempt recipient, if such holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, such backup withholding tax requirements. Any amounts withheld under the backup withholding rules will 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.

Foreign Asset Reporting

Certain U.S. Holders who are individuals are required to report information relating to an interest in our ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. 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 ADSs.

Foreign Account Tax Compliance Act

FATCA imposes withholding tax on certain types of payments made to foreign financial institutions and certain other non-U.S. entities. The legislation imposes a 30% withholding tax on dividends on, or, subject to the discussion of certain proposed Treasury Regulations below, gross proceeds from the sale or other disposition of, our ADSs paid to a "foreign financial institution" or to certain "non-financial foreign entities" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (i) above, it must enter into an agreement with the U.S. Treasury requiring, among other things, that it undertake to identify accounts held by "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on payments to account holders whose actions prevent it from complying with these reporting and other requirements. If the country in which a payee is resident has entered into an "intergovernmental agreement" with the United States regarding FATCA, that agreement may permit the payee to report to that country rather than to the U.S. Department of the Treasury. The U.S. Treasury recently released proposed Treasury Regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock or ADSs. In its preamble to such proposed Treasury Regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. Holders of our ADSs should consult their own tax advisors regarding the possible impact of these rules on their investment in our ADSs, and the possible impact of these rules on the entities through which they hold our ADSs, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of this 30% withholding tax under FATCA.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A HOLDER OF OUR SECURITIES. EACH HOLDER OF OUR SECURITIES IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE PARTICULAR TAX CONSEQUENCES TO SUCH HOLDER OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES IN LIGHT OF THE HOLDER'S OWN CIRCUMSTANCES.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are required to file reports and other information with the SEC under the Exchange Act, and the regulations thereunder applicable to foreign private issuers. We also furnish to the SEC under cover of Form 6-K material information required to be made public in Israel, filed with and made public by any stock exchange or distributed by us to our shareholders. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are available to the public through this web site at http://www.sec.gov. These SEC filings are also generally available to the public on (i) the Israel Securities Authority's Magna website at www.magna.isa.gov.il, (ii) the Tel Aviv Stock Exchange website at http://www.maya.tase.co.il, and (iii) from commercial document retrieval services.

As a foreign private issuer, we are exempt from the rules under the Exchange Act relating to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we file with the SEC, within 120 days after the end of each fiscal year ending December 31, an annual report on Form 20-F containing financial statements which are examined and reported on, with an opinion expressed, by an independent registered public accounting firm. We also furnish to the SEC under cover of Form 6-K material information required to be made public in Israel, filed with and made public by any stock exchange or distributed by us to our shareholders. In addition, in accordance with the NASDAQ Listing Rules, as a foreign private issuer we are required to submit on a Form 6-K an interim balance sheet and income statement as of the end of the second quarter of each fiscal year.

We maintain a corporate website at www.purple-biotech.com. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report. We have included our website address in this annual report solely as an inactive textual reference. We will post on our website any materials required to be posted on such website under applicable corporate or securities laws and regulations, including posting any notices of general meetings of our shareholders.

Any statements in this Annual Report on Form 20-F about any of our agreements, contracts or other documents is not necessarily complete. If the agreement, contract or document is filed as an exhibit to this Annual Report on Form 20-F, the agreement, contract or document is deemed to modify the description contained in this annual report. We urge you to review the exhibits themselves for a complete description of the contract or document.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our financial position, results of operations or cash flows. Our overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on our financial performance.

Risk of Interest Rate Fluctuation and Credit Exposure Risk

We do not anticipate undertaking any significant long-term borrowings. At present, our credit and interest risk arises from cash and cash equivalents, deposits with banks as well as accounts receivable. A substantial portion of our liquid instruments is invested in short-term deposits with Bank Leumi le-Israel Ltd. and Bank Mizrachi-Tefachot, major Israeli banking institutions, as well as with Bank Leumi USA.

We estimate that because the liquid instruments are invested mainly for the short-term in bank deposits, the credit and interest risk associated with these balances is immaterial. The primary objective of our investment activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing risk and loss. Our investments are exposed to market risk due to fluctuations in interest rates, which may affect our interest income and the fair market value of our investments. We manage this exposure by performing ongoing evaluations of our investments.

Equity Price Risk

We are not exposed to equity securities price risk because we have never invested in equity securities.

Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the U.S. dollar, our functional and reporting currency, mainly against the NIS and other currencies. Although the U.S. dollar is our functional currency and reporting currency, a portion of our expenses are denominated in NIS. Our NIS expenses consist principally of payments to employees or service providers, rent and short-term investments in NIS. We anticipate that a sizable portion of our expenses will continue to be denominated in currencies other than the U.S. dollar. If the U.S. dollar fluctuates significantly against the NIS it may have a negative impact on our results of operations. We manage our foreign exchange risk by aligning the currencies for holding short term investments with the currencies of expected expenses, based on our expected cash flows.

Portfolio diversification is performed based on risk level limits that we set. To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

Set forth below is a sensitivity test to possible changes in U.S. dollars/NIS exchange rate as of December 31, 2020:

Sensitive instrument	Income (loss) from change in exchange rate (U.S. dollars in thousands)		Value (U.S. dollars in thousands)	Income (loss) from change in exchange rate (U.S. dollars in thousands)	
	Down 2%	Down 5%		Up 5%	Up 2%
Cash and cash equivalents and deposits	10	24	489	(24)	(10)
Other current assets	30	75	1,500	(75)	(30)
Accounts payable	(10)	(26)	(524)	26	10
Other payables	(40)	(100)	(1,991)	100	40
Post employment benefit liabilities	(5)	(13)	(265)	13	5
Total income (loss)	(15)	(40)		40	15

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Each of the American Depositary Shares, or ADSs, represents ten ordinary shares (or a right to receive ten ordinary shares). The ADSs trade on the NASDAQ Capital Market.

The form of the deposit agreement for the ADSs and the form of American Depositary Receipt (ADR) that represents an ADS have been incorporated by reference as exhibits to this Annual Report on Form 20-F. Copies of the deposit agreement are available for inspection at the principal office of The Bank of New York Mellon, located at 101 Barclay Street, New York, New York 10286.

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:	***For:***
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

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

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

We have performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that the material financial and non-financial information required to be disclosed to the SEC is recorded, processed, summarized and reported timely. Based on our evaluation, our management, including the chief executive officer and chief financial officer, has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report, were effective.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) promulgated under the Exchange Act. Our internal control system was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation and fair presentation of published financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation and 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 policies or procedures may deteriorate.

Our management, including the chief executive officer and chief financial officer, conducted an evaluation, pursuant to Rule 13a-15(c) promulgated under the Exchange Act, of the effectiveness, as of the end of the period covered by this Annual Report, of its internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013). Based on the results of this evaluation, management concluded that as at December 31, 2020 our internal control over financial reporting was effective.

Notwithstanding the foregoing, there can be no assurance that our controls and procedures will detect or uncover all failures in our controls over measurement and disclosure in our financial statements or detect instances of fraud, if any.

(c) Attestation Report of Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by Somekh Chaikin, a member of KPMG International, our independent registered public accounting firm, as stated in their report included with our consolidated financial statements included elsewhere in this Annual Report on Form 20-F.

(d) Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that each of Mr. Steinberg and Ms. Stern-Raff are audit committee financial experts as defined by the SEC rules and have the requisite financial experience as defined by the NASDAQ Listing Rules. Our board of directors has also determined that Dr. Rowinsky, Mr. Agmon, Mr. Steinberg and Ms. Stern-Raff qualify as independent directors under the corporate governance standards of the NASDAQ Listing Rules and the independence requirements of Rule 10A-3 of the Exchange Act.

ITEM 16B. CODE OF ETHICS

Our Board of Directors adopted a Code of Business Conduct and Ethics (the "Code") that applies to all our employees, including without limitation our chief executive officer, chief financial officer and controller. A copy of the Code may be viewed on our website at www.purple-biotech.com. It is our intention for the code of ethics to remain accessible on our website for as long as we remain subject to the requirements of this Item and choose to comply with this Item by posting the Code on our website. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report on Form 20-F and is not incorporated by reference herein. There have been no changes to our code of ethics since our most recent Annual Report Form 20-F.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the approximate total compensation that was expensed by the Company and its subsidiaries to the Company's independent auditors, Somekh Chaikin, a member of KPMG International, our independent registered public accounting firm, for each of the years ended December 31, 2020 and 2019:

	2020	2019
	(in thousands of U.S. dollars)	
Audit fees [(1)]	126	81
Tax [(2)]	17	35
Total	143	116

(1) "Audit fees" include fees for services performed in connection with the Company's annual audit, certain procedures regarding the Company's interim financial results, fees related to our public offerings and registration statements, and consultation concerning financial accounting and reporting standards.
(2) Tax fees relate to services provided regarding tax compliance and review of tax returns.

All of the audit services and tax services described in the table above were approved in advance by the audit committee in accordance with paragraph (c)(7)(i)(B) of Rule 2-01 of Regulation S-X.

Audit committee's pre-approval policies and procedures

Under the Companies Law and our amended and restated articles of association, our shareholders are authorized to appoint our independent auditors. Under the Companies Law and our amended and restated articles of association, the shareholders may appoint our independent auditors to hold office for a longer period of time that will not extend beyond the end of the third annual meeting following that at which the auditor was appointed. At our 2020 annual general meeting of the shareholders, our shareholders appointed Somekh Chaikin, , a member of KPMG International, as our independent registered public accounting firm, for such longer period of time not to extend beyond the 2023 annual general meeting at which time the appointment of an auditor will be presented to the shareholders once again.

Under the Companies Law and our amended and restated articles of association, the board of directors is authorized to determine the independent auditor's remuneration. In addition, SEC rules require that a listed company's audit committee pre-approve the appointment and remuneration of the independent auditor. Our amended and restated articles of association include a provision which states that for so long as our securities are listed for trading on an exchange in the United States, such authority of the board of directors to set the remuneration of the auditor for audit activity and/or for additional services to us not being audit-related, will be deemed to have been delegated by the board of directors to the audit committee of the board of directors.

The advance approval of the Audit Committee is required for all audit and non-audit services provided by our auditors. All services provided by our auditors are approved in advance by the Audit Committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES.

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS.

Not applicable

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT.

Not applicable

ITEM 16G. CORPORATE GOVERNANCE

As a foreign private issuer, we are permitted to follow Israeli corporate governance practices instead of certain NASDAQ Listing Rules, provided that we disclose which requirements we are not following and the equivalent Israeli requirement. We currently rely on this "foreign private issuer exemption" with respect to the following items:

- *Distribution of annual and quarterly reports to shareholders*. Under Israeli law, as a public company whose shares are traded on the TASE, we are not required to distribute annual and quarterly reports directly to shareholders and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports publicly available through the website of the Israeli Securities Authority and the TASE. In addition, we make our audited financial statements available to our shareholders at our offices.

- *Compensation of Officers.* We comply with the requirements set forth under the Companies Law with respect to the approval of officer compensation. For a discussion regarding the approvals required under the Companies Law and the regulations promulgated thereunder for the approval of compensation of the chief executive officer, all other executive officers and directors, see "Item 6.C – Board Practices – Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law".

- *Shareholder Approval.* We seek shareholder approval for all corporate actions requiring such approval in accordance with the requirements of the Companies Law, which are different from the shareholder approval requirements under the NASDAQ Listing Rules, including NASDAQ Listing Rule 5635. The NASDAQ Listing Rules require that we obtain shareholder approval for certain dilutive events, such as (i) for the establishment or amendment of certain equity-based compensation plans and arrangements, (ii) issuances that will result in a change of control of a company, (iii) certain transactions other than a public offering involving issuances of 20% or more of the shares or voting power in a company, and (iv) certain acquisitions of the stock or assets of another company involving issuances of 20% or more of the shares or voting power in a company or if any director, officer or holder of 5% or more of the shares or voting power of the company has a 5% or greater interest in the company or assets to be acquired or consideration to be paid and the transaction could result in an increase in the outstanding common shares or voting power by 5% or more.

Under the Companies Law, shareholder approval is required for any transaction, including any grant of equity-based compensation, to a director or a controlling shareholder, but is not generally required to establish or amend an equity-based compensation plan. We will attempt to seek shareholder approval for our stock option or equity-based compensation plans (and the relevant annexes thereto) to the extent required in order to ensure they are tax qualified for any employees in the U.S. or who are U.S. citizens. However, even if such approval is not received, then the stock option or equity-based compensation plans will continue to be in effect, but we will be unable to grant to our U.S. resident and/or citizen employees options that qualify as Incentive Stock Options for U.S. federal tax purpose. Our stock option or other equity-based compensation plans are also available to our non-U.S. employees, and provide features necessary to comply with applicable non-U.S. tax laws. Similarly, shareholder approval is required under Israeli law for a private placement that is deemed a "extraordinary private placement" or that involves a director or controlling shareholder. A "extraordinary private placement" is a private placement in which a company issues securities representing 20% or more of its voting rights prior to the issuance and the consideration received pursuant to such issuance is not comprised, in whole or in part, solely of cash or securities registered for trade on an exchange or which is not made pursuant to market conditions, and as a result of which the shareholdings of a 5% holder of the shares or voting rights of the company increases or as a result of which a person will become a holder of 5% of the shares or voting rights of the company or a controlling shareholder after the issuance.

- *Approval of Related Party Transactions*. All related party transactions are approved in accordance with the requirements and procedures for approval of interested party acts and transactions, set forth in sections 268 to 275 of the Companies Law, and the regulations promulgated thereunder, which require the approval of the audit committee, the compensation committee, the board of directors and shareholders, as may be applicable, for specified transactions, rather than approval by the audit committee or other independent body of our Board of Directors as required under the NASDAQ Listing Rules.

- *Quorum of Shareholder Meetings.* Under the NASDAQ Listing rules, the quorum required for an ordinary meeting of shareholders consists of 33 1/3% of the issued share capital. As permitted under the Companies Law, pursuant to our amended and restated articles of association, the quorum required for a meeting of our shareholders consists of at least two shareholders present in person or by proxy who hold or represent at least 25% of the voting rights of our shares (and in an adjourned meeting, with some exceptions, any number of shareholders), instead of 33 1/3% of the issued share capital required under the NASDAQ Listing Rules

- *Nominations Committee and Nominations of our Directors.* Under Israeli law and our amended articles of association, our directors are not required to be selected, or recommended for board of director selection, by independent directors constituting a majority of the board's independent directors or by a nominations committee comprised solely of independent directors, as required by the NASDAQ Listing Rules. With the exception of directors elected by our Board of Directors due to vacancy, our directors are elected by an annual general meeting of our shareholders to hold office until the next annual meeting following three years from his or her election. The nominations for directors, which are presented to our shareholders, are generally made by our directors, but nominations may be made by one or more of our shareholders as provided in our amended and restated articles of association and under the Companies Law. However, in September 2020, we established a non-independent nominations committee whose role is (among other things) to identify and recommend to our board of directors for selection, director nominees, consistent with criteria approved by the board of directors.

Except as stated above, we currently intend to comply with the rules generally applicable to U.S. domestic companies listed on NASDAQ. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other NASDAQ Listing Rules related to corporate governance.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable

PART III

ITEM 17. FINANCIAL STATEMENTS

The Registrant has responded to Item 18 in lieu of responding to this Item.

ITEM 18. FINANCIAL STATEMENTS

See our consolidated financial statements as of December 31, 2020 and 2019 and for the three-year period ended December 31, 2020, beginning on page F-1.

ITEM 19. EXHIBITS

The exhibits filed with or incorporated into this Annual Report on Form 20-F are listed in the index of exhibits below:

Exhibit Number	Exhibit Description
1.1	Memorandum of Association of the Registrant (originally filed as Exhibit 99.3 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on December 10, 2020 and incorporated herein by reference thereto).
1.2	Amended and Restated Articles of Association of the Registrant (originally filed as Exhibit 99.2 to the Registrant's Form 6-K furnished to with the Securities and Exchange Commission on December 10, 2020 and incorporated herein by reference thereto).
2.1	Description of Share Capital
2.2	Form of Deposit Agreement among the Registrant, the Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued hereunder (incorporated by reference to Exhibit 4.1 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on September 24, 2015).
2.4	Form of American Depositary Receipt (incorporated by reference to prospectus filed with the Securities and Exchange Commission on August 14, 2020).
2.5	Form of Underwriters' Warrant (incorporated by reference to Exhibit 4.4 to our Registration Statement on Form F-1/A as filed with the Securities and Exchange Commission on November 18, 2015).
2.6	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on June 27, 2016).
2.8	Stock Purchase Agreement, dated January 12, 2017, by and between the Registrant and Goldman Hirsh Partners Ltd. (incorporated by reference to Exhibit 2.8 to the Registrant's Annual Report on Form 20-F as filed with the Securities and Exchange Commission on May 1, 2017).
2.9	Form of Warrant issued to purchasers in the July 2017 offering (incorporated by reference to Exhibit 4.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on July 14, 2017)
2.10	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on July 14, 2017)
2.11	Stock Purchase Agreement, dated October 3, 2017, by and among the Registrant, Certain Stockholders of TyrNovo Ltd. and the Stockholders' Representative (incorporated by reference to Exhibit 2.13 to the Registrant's Annual Report on Form 20-F as filed with the Securities and Exchange Commission on March 5, 2018)
2.12	Form of Warrant issued to purchasers in the June 2018 offering (incorporated by reference to Exhibit 4.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on June 5, 2018)
2.13	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on June 5, 2018)
2.14	Form of Warrant issued to purchasers in the January 2019 offering (incorporated by reference to Exhibit 4.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on January 18, 2019)
2.15	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on January 18, 2019)
2.16	Form of Shareholder Undertaking and Agreement, dated January 7, 2020, between Purple Biotech Ltd. and the shareholders signatory thereto (incorporated by reference to Exhibit 4.17 to the Registrant's Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on March 10, 2020)

2.17	Form of Warrant, dated January 7, 2020, between Purple Biotech Ltd. issued to former FameWave shareholders (incorporated by reference to Exhibit 4.18 to the Registrant's Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on March 10, 2020)
2.18	Form of Ordinary Warrant issued to purchasers in the March 2020 public offering (incorporated by reference to Exhibit 4.19 to the Registrant's Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on March 10, 2020)
2.19	Form of Pre-funded Warrant issued to purchasers in the March 2020 public offering (incorporated by reference to Exhibit 4.20 to the Registrant's Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on March 10, 2020)
2.20	Form of Placement Agent Warrant issued to Placement Agent in the March 2020 public offering (incorporated by reference to Exhibit 4.21 to the Registrant's Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on March 10, 2020)
2.21	Form of Warrant issued to investors in the April 2020 private placement (incorporated by reference to Exhibit 99.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on April 20, 2020)
2.22	Form of Placement Agent Warrant issued to Placement Agent in the April 2020 private placement (incorporated by reference to Exhibit 99.2 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on April 20, 2020)
2.23	Form of Warrant issued to investors in the May 2020 private placement (incorporated by reference to Exhibit 4.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on May 8, 2020)
2.24	Form of Placement Agent Warrant issued to Placement Agent in the May 2020 public offering (incorporated by reference to Exhibit 4.2 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on May 8, 2020)
2.25	Form of Warrant issued to purchasers in the June 2020 offering (incorporated by reference to Exhibit 4.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on June 25, 2020)
2.26	Form of Placement Agent Warrant issued to Placement Agent in the June 2020 public offering (incorporated by reference to Exhibit 4.2 to the Registrant's Form 6-K/A furnished to the Securities and Exchange Commission on June 29, 2020)
4.1	Form of Letter of Exemption adopted on July 2013 (unofficial English translation from Hebrew) (incorporated by reference to Exhibit 10.5 to our Registration Statement on Form F-1 filed with the Securities and Exchange Commission on September 24, 2015).
4.2	Form of Letter of Indemnity adopted on July 2013 (unofficial English translation from Hebrew) (incorporated by reference to Exhibit 10.6 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on September 24, 2015).
4.3	Purple Biotech Ltd. 2016 Equity-Based Incentive Plan, as amended
4.4	Form of Share Purchase Agreement between Purple Biotech and the purchasers (incorporated by reference to Exhibit 1.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on June 29, 2016)
4.4*	License Agreement, dated as of August 15, 2013, by and between Yissum Research Development Company of The Hebrew University of Jerusalem, Ltd. and TyrNovo Ltd. (incorporated by reference to Exhibit 4.14 to the Registrant's Annual Report on Form 20-F as filed with the Securities and Exchange Commission on May 1, 2017)
4.6*	First Amendment to License Agreement, dated as of April 8, 2014, by and between Yissum Research Development Company of The Hebrew University of Jerusalem, Ltd. and TyrNovo Ltd. (incorporated by reference to Exhibit 4.15 to the Registrant's Annual Report on Form 20-F as filed with the Securities and Exchange Commission on May 1, 2017)
4.7*	Second Amendment to License Agreement, dated as of March 16, 2017, by and between Yissum Research Development Company of The Hebrew University of Jerusalem, Ltd. and TyrNovo Ltd. (incorporated by reference to Exhibit 4.16 to the Registrant's Annual Report on Form 20-F as filed with the Securities and Exchange Commission on May 1, 2017)
4.8	Form of Securities Purchase Agreement dated as of July 11, 2017 by and between the Registrant and the purchasers in the offering (incorporated by reference to Exhibit 1.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on July 14, 2017)
4.9	Purple Biotech Ltd. Office Holder Compensation Policy approved the shareholders on August 6, 2020 (incorporated by reference to Exhibit A to the Proxy Statement included as Exhibit 99.1 to the Registrant's Form 6-k furnished to the Securities and Exchange Commission on July 2, 2020)
4.10	Revolving Secured Facility and Pledge Agreement dated March 1, 2017 by and between TyrNovo Ltd., and Purple Biotech Ltd. (incorporated by reference to Exhibit 4.18 to the Registrant's Annual Report on Form 20-F as filed with the Securities and Exchange Commission on March 5, 2018)
4.11	Form of Securities Purchase Agreement dated as of June 1, 2018 by and between the Registrant and the purchasers in the offering (incorporated by reference to Exhibit 1.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on June 5, 2018)

4.12	Form of Securities Purchase Agreement dated as of January 16, 2019 by and between the Registrant and the purchasers in the offering (incorporated by reference to Exhibit 1.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on January 18, 2019)
4.13**	Product Manufacturing Agreement, effective as of November 8, 2018, by and between Purple Biotech Ltd. and Dexcel Ltd. (incorporated by reference to Exhibit 4.15 to the Registrant's Annual Report on Form 20-F/A as filed with the Securities and Exchange Commission on April 3, 2019)
4.14**	Agreement dated as of December 27, 2018, by and between Purple Biotech Ltd. and Coeptis Pharmaceuticals Inc. (incorporated by reference to Exhibit 4.16 to the Registrant's Annual Report on Form 20-F/A as filed with the Securities and Exchange Commission on April 3, 2019).
4.15**	Stock Purchase Agreement by and among Purple Biotech Ltd., The Stockholders of FameWave Ltd. and M. Arkin (1999) Ltd. dated as of March 14, 2019 (incorporated by reference to Exhibit 4.17 to the Registrant's Annual Report on Form 20-F/A as filed with the Securities and Exchange Commission on April 3, 2019).
4.16	English Translation of Enforcement Arrangement entered into by and amongst the Israel Securities Authority, Purple Biotech Ltd., Isaac Israel, Paul Waymack, and Simcha Rock (incorporated by reference to Exhibit 99.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on August 13, 2019)
4.17	Amendment dated August 16, 2019 to the Stock Purchase Agreement by and among Purple Biotech Ltd., The Stockholders of FameWave Ltd. and M. Arkin (1999) Ltd. dated as of March 14, 2019 (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form F-1 filed with the Securities and Exchange Commission on September 16, 2019).
4.18 **	Amendment dated October 8, 2019, to the Agreement by and between Purple Biotech Ltd. and Coeptis Pharmaceuticals Inc (incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form F-3 filed with the Securities and Exchange Commission on December 2, 2019).
4.19	Form of Lock-Up and Registration Rights Agreement, dated January 7, 2020, between Purple Biotech Ltd. and the sellers listed on Exhibit A thereto (incorporated by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on March 10, 2020)
4.20	Form of Securities Purchase Agreement dated as of March 12, 2020 by and between the Registrant and the purchasers in the March 2020 public offering (incorporated by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on March 10, 2020)
4.21**	Amended and Restated License effective as of the 25th day of May, 2010 by and between: Tel Hashomer - Medical Research, Infrastructure and Services LTD and Ramot at Tel Aviv University Ltd. and cCAM Biotherapeutics Ltd. (incorporated by reference to Exhibit 4.23 to the Registrant's Annual Report on Form 20-F/A as filed with the Securities and Exchange Commission on March 31, 2020).
4.22**	First Amendment to Amended and Restated License Agreement, by and between Tel Hashomer – Medical Research, Infrastructure and Services Ltd., Ramot at Tel Aviv University Ltd. and cCAM Biotherapeutics Ltd. (incorporated by reference to Exhibit 4.24 to the Registrant's Annual Report on Form 20-F/A as filed with the Securities and Exchange Commission on March 31, 2020)
4.23	Second Amendment to Amended and Restated License Agreement, by and between Tel Hashomer – Medical Research, Infrastructure and Services Ltd., Ramot at Tel Aviv University Ltd. and cCAM Biotherapeutics Ltd. (incorporated by reference to Exhibit 4.25 to the Registrant's Annual Report on Form 20-F/A as filed with the Securities and Exchange Commission on March 31, 2020)
4.24	Assignment and Assumption Agreement effective as of March 21, 2019, between Tel Hashomer – Medical Research, Infrastructure and Services Ltd., Ramot at Tel Aviv University Ltd., FameWave Ltd. and cCAM Biotherapeutics Ltd. (incorporated by reference to Exhibit 4.26 to the Registrant's Annual Report on Form 20-F/A as filed with the Securities and Exchange Commission on March 31, 2020).
4.25**	Master Development Services Agreement between FameWave Ltd., and Rentschler Biopharma SE executed on March 17, 2020 (incorporated by reference to Exhibit 4.27 to the Registrant's Annual Report on Form 20-F/A as filed with the Securities and Exchange Commission on March 31, 2020)
4.26	Form of Warrant Exercise Agreement, dated as of April 19, 2020, entered into between the Registrant and the warrant holders in the April 2020 private placement (incorporated by reference to Exhibit 99.4 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on April 20, 2020)
4.27	Form of Securities Purchase Agreement dated as of May 6, 2020 by and between the Registrant and the purchasers in the May 2020 offering (incorporated by reference to Exhibit 1.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on May 8, 2020)
4.28	Form of Securities Purchase Agreement dated as of June 23, 2020 by and between the Registrant and the purchasers in the June 2020 offering (incorporated by reference to Exhibit 1.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on June 25, 2020)
4.29**	First Amendment to Product Manufacturing Agreement, effective as of May 17, 2020, by and between Purple Biotech Ltd. and Dexcel Ltd.
8.1	List of subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on March 10, 2020).
12.1	Certification by Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
12.2	Certification by Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
13.1	Certification by Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
13.2	Certification by Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1	Consent of Somekh Chaikin, independent registered public accounting firm, a Member Firm of KPMG International.

* Confidential treatment granted with respect to portions of this Exhibit.

** Portions of this exhibit have been omitted because they are both (i) not material, and (ii) would likely cause competitive harm to the Company if publicly disclosed.

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 Form 20-F on its behalf.

PURPLE BIOTECH LTD.

By: /s/ Isaac Israel
Name: Isaac Israel
Title: Chief Executive Officer

By: /s/ Gil Efron
Name: Gil Efron
Title: Chief Financial Officer

Date: March 15, 2021

Purple Biotech Ltd.

Consolidated Financial Statements

As of December 31, 2020

Consolidated Financial Statements as at December 31, 2020

Contents

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Purple Biotech Ltd.:

Opinions on the Consolidated Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated statements of financial position of Purple Biotech Ltd. and its subsidiaries (hereinafter – "the Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and other comprehensive loss, changes in equity, and cash flows for each of the years in the three year period ended December 31, 2020, and the related notes (collectively, "the consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2020, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020 based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Change in Accounting Principle

As discussed in Note 3N to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2019, due to the adoption of International Financial Reporting Standard No. 16 Leases.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, 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 consolidated financial statements and an opinion on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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.

Critical Audit Matter

As discussed in Notes 3D and 5 to the consolidated financial statements, intangible assets, consisting of in-process research and development (IPR&D), were USD 20,482 thousand as of December 31, 2020. IPR&D is related to the TyrNovo and FameWave acquisitions. The Company tests intangible assets for impairment on an annual basis, or more frequently if there are indications of impairment.

We identified the assessment of the fair value of the intangible assets as part of the annual impairment test as a critical audit matter. Specifically, the key assumptions used in the assessments are future expenses for completing development of the intangible assets, future revenues, success rate and discount rate. Evaluation of the key assumptions involved a high degree of subjective auditor judgment, including the involvement of valuation professionals with specialized skills and knowledge, as changes to the assumptions could have had a significant effect on the Company's assessment of the fair value of its intangible assets.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls over the Company's process related to the determination of the fair value of intangible assets, including controls over the key assumptions described above. We assessed the Company's estimate of future expenses through a combination of inquiry of finance and operations personnel and by comparing estimated future expenses to budgeted expenses approved by the board of directors and to industry data reports. We compared actual expenses for developing the TyrNovo IPR&D in the current year to the amount originally forecasted, in order to assess the Company's ability to accurately forecast. We compared the Company's estimate of future revenues and the success rate assumption to industry data reports. We performed a sensitivity analysis over future revenues, the success rate, and discount rate assumptions by considering the effect of a range of results. We involved valuation professionals with specialized skills and knowledge, who assisted in evaluating the Company's discount rate by comparing it to discount rate ranges that were independently developed using third-party market data for comparable entities.

Somekh Chaikin
Member Firm of KPMG International

We have served as the Company's auditor since 2011.
Tel-Aviv, Israel
March 15, 2021

Consolidated Statements of Financial Position as of December 31,

	Note	2020 USD thousands	2019 USD thousands
Assets			
Cash and cash equivalents	6, 21A	**11,247**	4,385
Short term deposits	21A	**46,558**	10
Trade receivables		**500**	-
Financial assets	21B	**-**	2,000
Other current assets	8	**977**	1,907
Total current assets		**59,282**	8,302
Non-current assets			
Right to use assets	7	**790**	206
Fixed assets, net		**178**	38
Long term deposits	21A	**3,071**	-
Intangible assets	5	**20,482**	6,172
Total assets		**83,803**	14,718
Liabilities			
Lease liability - short term	7	**207**	195
Accounts payable		**1,198**	1,245
Other payables	9	1,693	2,106
Total current liabilities		**3,098**	3,546
Non-current liabilities			
Lease liability	7	**688**	28
Post-employment benefit liabilities	20	**265**	285
Total non - current liabilities		**953**	313
Equity			
Share capital, no par value		-	-
Share premium	10	**118,909**	46,986
Receipts on account of warrants	10	**29,984**	9,874
Capital reserve for share-based payments	11	**8,115**	3,181
Capital reserve from transactions with related parties		**761**	761
Capital reserve from transactions with non- controlling interest	5A	**(859)**	(859)
Accumulated loss		**(77,521)**	(49,522)
Equity attributable to owners of the Company		**79,389**	10,421
Non-controlling interests		**363**	438
Total equity		**79,752**	10,859
Total liabilities and equity		**83,803**	14,718

The accompanying notes are an integral part of these consolidated financial statements.

Consolidated Statements of Operations

	Note	For the year ended December 31 2020 USD thousands	2019 USD thousands	2018 USD thousands
Revenues	14	**1,000**	1,000	1,000
Research and development expenses	15	**7,488**	2,674	5,268
Sales, general and administrative expenses	16	**6,306**	6,078	5,195
Reimbursement of legal fees	16B	**(182)**	(596)	(743)
Other income	17	**-**	-	(894)
Total operating expenses		**13,612**	8,156	8,826
Operating Loss		**12,612**	7,156	7,826
Expenses (income) on account of warrants	18A	**15,655**	(1,509)	(2,740)
Finance expense	18B	**61**	181	576
Finance income		**(254)**	(151)	(93)
Finance expenses (income), net		**15,462**	(1,479)	(2,257)
Taxes expenses, net	19C	-	216	-
Loss for the year		**28,074**	5,893	5,569
Loss attributable to:				
Owners of the Company		**27,999**	5,850	5,200
Non-controlling interests		**75**	43	369
		28,074	5,893	5,569
Loss per share data				
Basic and diluted loss per ADS - USD		**2.44**	(*) 3.00	(*) 3.90
Number of shares used in calculating basic and diluted loss per ADS		**11,500,113**	(*) 1,936,778	(*) 1,420,530

(*) Restated to reflect a 1:10 reverse ratio of the ADSs, that took place in August 2020, see Note 10A.

The accompanying notes are an integral part of these consolidated financial statements.

Consolidated Statements of Changes in Equity

	Share Capital	Share premium	Receipts on account of warrants	Capital reserve for share-based payments	Capital reserve from transactions with related parties	Capital reserve from transactions with Non-controlling interest	Accumulated loss	Total	Non-controlling interests	Total equity
	USD thousands									
Balance as of January 1, 2020	-	46,986	9,874	3,181	761	(859)	(49,522)	10,421	438	10,859
Transactions with owners of the Company:										
Issuance of American Depository Shares (ADSs) on the NASDAQ, net of issuance costs	-	21,200	14,825	2,723	-	-	-	38,748	-	38,748
Exercise of warrants	-	38,013	(23,780)	455	-	-	-	14,688	-	14,688
Share-based payments	-	889	-	1,756	-	-	-	2,645	-	2,645
Transfer of derivative instrument from liability to equity (see Note 10D)	-	-	27,386	-	-	-	-	27,386	-	27,386
ADS and warrants issued in connection with the purchase of a subsidiary (see Note 5B)	-	11,821	1,679	-	-	-	-	13,500	-	13,500
Total transactions with owners of the Company		71,923	20,110	4,934	-	-	-	96,967		96,967
Loss for the year	-	-	-	-	-	-	(27,999)	(27,999)	(75)	(28,074)
Balance as of December 31, 2020	-	118,909	29,984	8,115	761	(859)	(77,521)	79,389	363	79,752

The accompanying notes are an integral part of these consolidated financial statements.

Consolidated Statements of Changes in Equity

	Share Capital	Share premium	Receipts on account of warrants	Capital reserve for share-based payments	Capital reserve from transactions with related parties	Capital reserve from transactions with Non-controlling interest	Accumulated loss	Total	Non-controlling interests	Total equity
	USD thousands									
Balance as of January 1, 2019	-	44,597	7,982	1,714	761	(859)	(43,672)	10,523	481	11,004
Transactions with owners of the Company:										
Issuance of American Depository Shares (ADSs) on the NASDAQ, net of issuance costs	-	2,200	-	298	-	-	-	2,498	-	2,498
Issuance of shares due to RSUs vesting	-	104	-	(104)	-	-	-	-	-	-
Exercise of warrants	-	85	(42)	-	-	-	-	43	-	43
Share-based payments	-	-	-	1,273	-	-	-	1,273	-	1,273
Transfer of derivative instrument from liability to equity (see Note 10D)	-	-	1,934	-	-	-	-	1,934	-	1,934
Total transactions with owners of the Company	-	2,389	1,892	1,467	-	-	-	5,748	-	5,748
Loss for the year	-	-	-	-	-	-	(5,850)	(5,850)	(43)	(5,893)
Balance as of December 31, 2019	-	46,986	9,874	3,181	761	(859)	(49,522)	10,421	438	10,859

The accompanying notes are an integral part of these consolidated financial statements.

Consolidated Statements of Changes in Equity

	Share Capital	Share premium	Receipts on account of warrants	Capital reserve for share-based payments	Capital reserve from transactions with related parties	Capital reserve from transactions with Non-controlling interest	Accumulated loss	Total	Non-controlling interests	Total equity
	USD thousands									
Balance as of January 1, 2018	-	35,979	7,415	1,725	761	-	(38,472)	7,408	1,280	8,688
Transactions with owners of the Company:										
Issuance of American Depository Shares (ADSs) on the NASDAQ, net of issuance costs	-	4,276	-	-	-	-	-	4,276	-	4,276
Issuance of shares due to RSUs vesting	-	299	-	(299)	-	-	-	-	-	-
Exercise of warrants	-	2,133	-	-	-	-	-	2,133	-	2,133
Share issuance due to an acquisition of a subsidiary (see Note 5A)	-	1,856	-	-	-	(859)	-	997	(861)	136
Share-based payments	-	54	-	288	-	-	-	342	431	773
Transfer of derivative instrument from liability to equity	-	-	567	-	-	-	-	567	-	567
Total transactions with owners of the Company	-	8,618	567	(11)	-	(859)	-	8,315	(430)	7,885
Comprehensive loss for the year	-	-	-	-	-	-	(5,200)	(5,200)	(369)	(5,569)
Balance as of December 31, 2018	-	44,597	7,982	1,714	761	(859)	(43,672)	10,523	481	11,004

The accompanying notes are an integral part of these consolidated financial statements.

Consolidated Statements of Cash Flows for the year ended December 31,

	2020	2019	2018
		USD thousands	
Cash flows from operating activities:			
Loss for the year	**(28,074)**	(5,893)	(5,569)
Adjustments:			
Depreciation	**235**	178	7
Finance expenses (income), net	**15,462**	(1,479)	(2,257)
Share-based payments	**2,645**	1,273	773
Income in regards with settlement with a minority shareholder of a subsidiary (see Note 5A)	**-**	-	(894)
	(9,732)	(5,921)	(7,940)
Changes in assets and liabilities:			
Changes in trade receivables and other current assets	**501**	62	(1,111)
Changes in accounts payable	**(2,330)**	503	393
Changes in other payables	**(511)**	(77)	241
Changes in post-employment benefit liabilities	**(20)**	(148)	(63)
	(2,360)	340	(540)
Net cash used in operating activities	**(12,092)**	(5,581)	(8,480)
Cash flows from investing activities:			
Cash assumed as part of acquisition of FameWave (See Note 5B)	**69**	-	-
Investment in financial assets and loan granted (See Note 5B)	**-**	(2,100)	-
Decrease (increase) in short and long term deposits	**(49,618)**	1,511	1,967
Interest received	**110**	151	93
Acquisition of fixed assets	**(156)**	(11)	(16)
Net cash provided by (used in) investing activities	**(49,595)**	(449)	2,044
Cash flows from financing activities:			
Proceeds from issuance of ADSs	**27,925**	2,594	4,683
ADS issuance expenses paid	**(2,074)**	(264)	(407)
Proceeds from issuance of warrants	**26,574**	3,406	3,467
Warrants issuance expenses paid	**(3,281)**	(347)	(301)
Proceeds from exercise of warrant	**19,547**	43	515
Repayment of lease liability	**(179)**	(171)	
Interest paid	**(24)**	(28)	(169)
Net cash provided by financing activities	**68,488**	5,233	7,788
Net increase (decrease) in cash and cash equivalents	**6,801**	(797)	1,352
Cash and cash equivalents at the beginning of the year	**4,385**	5,163	3,947
Effect of translation adjustments on cash and cash aquivalents	**61**	19	(136)
Cash and cash equivalents at end of the year	**11,247**	4,385	5,163
Non- Cash activities:			
Reclassification of non-tradable derivatives until registered for trading	**27,386**	1,934	567

The accompanying notes are an integral part of these consolidated financial statements

Notes to the Consolidated Financial Statements

Note 1 - General

Reporting entity

A. Purple Biotech Ltd. (hereinafter: **"the Company**" or **"Purple"**) is a clinical-stage company advancing first-in-class therapies to overcome tumor immune evasion and drug resistance.

The Company has two operating segments:

(i) Oncology, which includes NT219, a therapeutic candidate which is a small molecule targeting the novel cancer drug resistance pathways IRS1/2 and STAT3. and CM24 a monoclonal antibody blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways.

(ii) Pain and Hypertension, which includes Consensi®, a combination drug approved by the FDA for marketing in the U.S and is partnered in the U.S, China and South Korea.

The Company was incorporated in Israel as a private company in August 1968, and has been listed for trading on the Tel Aviv Stock Exchange since September 1978. In October 2012, the Company disposed of all of its previous operations, and in July 2013, the Company acquired shares of Kitov Pharmaceuticals Ltd. (hereinafter: "**Kitov**") from its shareholders, in exchange for the Company's shares.

B. The Company's securities (American Depository Shares ("ADS") as well as Series A warrants) were listed for trading on the NASDAQ in November 2015. Each ADS represents 10 ordinary shares with no par value following a reverse split in effect from August 23, 2020 (see Note 10A). Each 10 warrants enables the purchase of 1 ADS.

In December 2020 the Company changed its name from Kitov Pharma Ltd to Purple Biotech Ltd.

The Company's address is 4 Oppenheimer St., Science Park Rehovot 7670104 Israel.

C. In January 2017, the Company acquired the majority of shares of TyrNovo Ltd. (hereinafter: "**TyrNovo**"). During 2018, the Company acquired additional shares of TyrNovo from various minority shareholders, see also Note 5A.

In January 2020, the Company acquired 100% of FameWave Ltd (hereinafter ""FameWave"), see also Note 5B.

The Company together with TyrNovo and FameWave are referred to, in these consolidated financial statements, as "**the Group**".

D. Since incorporation through December 31, 2020, the Group has incurred losses and negative cash flows from operations mainly attributed to its development efforts and has an accumulated deficit of USD 77.5 million. The Group has financed its operations mainly through private and public financing rounds. Through December 31, 2020, the Company raised a total of USD 93.8 million net (excluding exercise of warrants).

E. While the COVID-19 pandemic has affected our operations to date to a certain extent such as causing a slowdown in product sales and operation of clinical studies, the extent to which the COVID-19 pandemic may impact our operations in the future will depend on future developments. In particular, the continued spread of COVID-19 globally could materially adversely impact our operations and workforce, including our manufacturing activities, clinical trials and product sales, as well as our ability to continue to raise capital.

Notes to the Consolidated Financial Statements

Note 2 - Basis of Preparation of the Consolidated Financial Statements

A. Statement of compliance with International Financial Reporting Standards

The Group has prepared the consolidated financial statements in accordance with International Financial Reporting Standards (hereinafter: "IFRS"), as issued by the International Accounting Standard Board ("IASB").

These consolidated financial statements were approved by the board of directors on March 11, 2021.

B. Functional and presentation currency

These consolidated financial statements are presented in US dollars (USD), which is the Group's functional currency, rounded to the nearest one thousand, unless otherwise noted. The USD is the currency that represents the principal economic environment in which the Group operates.

C. Use of estimates and judgment

The preparation of consolidated financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

Management prepares the estimates on the basis of past experience, various facts, external circumstances, and reasonable assumptions according to the pertinent circumstances of each estimate. The preparation of accounting estimates used in the preparation of the Group's consolidated financial statements requires management of the Group to make assumptions regarding circumstances and events that involve considerable uncertainty. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Information about assumptions made by the Group with respect to the future and other reasons for uncertainty with respect to estimates that have a significant risk of resulting in a material adjustment to carrying amounts of assets and liabilities in the next financial year are included in the following notes:

Estimate	Principal assumptions	Possible effects	Reference
Fair value measurement of non-trading derivatives	Unobservable inputs used in the valuation model including standard deviation and discount rates	Profit or loss from a change in the fair value of derivative financial instruments	For information on a sensitivity analysis of level 3 financial instruments carried at fair value see Note 21B regarding financial instruments
Assessment of probability of contingent liabilities	Whether it is more likely than not that an outflow of economic resources will be required in respect of legal claims pending against the Company and its investees	Reversal or creation of a provision for a claim	For information on the Company's exposure to claims see Note 13B regarding contingent liabilities
Recoverability of intangible assets	The discounted cash flows method includes assumptions such as future expenses, future revenues, successes rate and discount rate.	impermanent of the In-process research and development in profit or loss	See Note 5 regarding subsidiaries

Note 2 - Basis of Preparation of the Consolidated Financial Statements (Cont'd)

Examination of existence of business	When acquiring an operation, the Group uses judgement to determine whether a "business" was acquired or the acquisition does not meet the definition of a "business". In order to do so the Group examines, inter alia, whether substantially all of the fair value of the acquired assets is attributable to a single identifiable asset or to a group of similar identifiable assets.	This decision may affect, inter alia, the recognition of transaction costs, deferred taxes, gain on bargain purchase, goodwill and future revaluation gains.	See Note 5 regarding subsidiaries.
Measurement of variable consideration	In order to determine the transaction price, the Group 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.	An increase or decrease in amounts of revenue recognized over the contract period.	See Note 14 regarding revenue
Determining the discount rate of a lease liability	The Group discounts the lease payments using its incremental borrowing rate.	An increase or decrease in the lease liability, right-to-use asset and depreciation and financing expenses recognized.	See Note 7 regarding leases
Determining the lease term	In order to determine the lease term, the Group takes into consideration the period over which the lease is non-cancellable, not including renewal options since it is reasonably certain it will exercise and/or termination options that it is reasonably certain it will not exercise.	An increase or decrease in the initial measurement of a right-to-use asset and lease liability and in depreciation and financing expenses in subsequent periods.	See Note 7 regarding leases

Fair value measurement

The Group's management regularly reviews significant unobservable inputs and valuation adjustments, including obtaining valuations prepared by third parties and assessing the evidence to support the conclusion that these valuations meet the requirements of IFRS, including the level in the fair value hierarchy in which the valuations should be classified.

Notes to the Consolidated Financial Statements

Note 2 - Basis of Preparation of the Consolidated Financial Statements (Cont'd)

Significant valuation issues are reported to the Group Audit Committee.

When measuring the fair value of an asset or liability, the Group uses market observable data as far as possible. Fair values are categorized into different levels in a fair value hierarchy based on the inputs used in the valuation techniques as follows:

- Level 1: quoted prices in active markets for identical assets or liabilities.
- Level 2: inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3: inputs for the asset or liability that are not based on observable market data.

If the inputs used to measure the fair value of an asset or a liability might be categorized in different levels of the fair value hierarchy, then the fair value measurement is categorized in its entirety in the same level of the fair value hierarchy as the lowest level input that is significant to the entire measurement.

Further information about the assumptions made in measuring fair value of share-based payments, intangible assets, financial asset, and derivative instruments are included in Note 11, Note 5 and Note 21B, respectively.

D. Exchange rates and linkage bases

Balances in foreign currency or linked thereto are included in the consolidated financial statements at the representative exchange rates, as published by the Bank of Israel, which were prevailing as of the statement of financial position date.

Data on exchange rates are as follows:

	Representative exchange rate of USD (NIS/USD 1)
Date of consolidated financial statements:	
December 31, 2020	3.215
December 31, 2019	3.456
December 31, 2018	3.748

Changes in exchange rates for the year ended:	**%**
December 31, 2020	(7)
December 31, 2019	(7.8)
December 31, 2018	8.1

E. Initial application of new standards, amendments to standards and interpretations

As from January 1, 2020 the Group applies the new amendments to IFRS 3, Business Combinations, see Note 3A for further information.

The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

Notes to the Consolidated Financial Statements

Note 3 - Significant Accounting Policies

The accounting policies set out below have been consistently applied for all periods presented in these consolidated financial statements:

A. Basis of consolidation

1. Business combination

The Group accounts for business combinations using the acquisition method when control is transferred to the Group. The consideration transferred in the acquisition is generally measured at fair value, as are the identifiable net assets acquired. Any goodwill that arises is tested annually for impairment. Any gain on a bargain purchase is recognized in profit or loss immediately. Transaction costs are expensed as incurred, except if related to the issue of debt or equity securities.

The consideration transferred does not include amounts related to the settlement of pre-existing relationships. Such amounts are generally recognized in profit or loss.

Amendment to IFRS 3, Business Combinations

The Amendment is effective for transactions to acquire an asset or business for which the acquisition date is in annual periods beginning on or after January 1, 2020.

The Amendment clarifies when a transaction to acquire an operation is the acquisition of a "business" and when it is the acquisition of a group of assets that according to the standard is not considered the acquisition of a "business". For the purpose of this examination, the Amendment added an optional concentration test so that if substantially all of the fair value of the acquired assets is attributable to a group of similar identifiable assets or to a single identifiable asset, this will not be the acquisition of a business. In addition, the minimum requirements for definition as a business have been clarified, and examples illustrating the aforesaid examination were added, such as for example the requirement that the acquired processes be substantive so that in order for it to be a business, the operation shall include at least one input element and one substantive process, which together significantly contribute to the ability to create outputs. Furthermore, the Amendment narrows the reference to the output's element required in order to meet the definition of a business and added examples illustrating the aforesaid examination.

The group applied this amendment for the FameWave acquisition transaction. For further information see Note 5B.

2. Subsidiaries

Subsidiaries are entities controlled by the Group. The Group controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The financial statements of subsidiaries are included in the consolidated financial statements from the date on which control commences until the date on which control ceases.

3. Non-controlling interests

Non-controlling interests are measured initially at their proportionate share of the acquiree's identifiable net assets at the date of acquisition.

Changes in the Group's interest in a subsidiary that do not result in a loss of control are accounted for as equity transactions.

4. Transactions eliminated on consolidation

Intra-group balances and transactions, and any unrealized income and expenses arising from intra-group transactions, are eliminated in preparing the consolidated financial statements.

Note 3 - Significant Accounting Policies (Cont'd)

B. Foreign currency transactions

Transactions in foreign currency are translated to the functional currency of the Group at exchange rates as of the transaction dates. Monetary assets and liabilities denominated in foreign currency as of the reporting date are translated into the functional currency at the exchange rate as of the said date. Exchange rate differences with respect to monetary items are the differences between the amortized cost in the functional currency as of the start of the year, adjusted for the effective interest during the year, and the amortized cost in foreign currency, translated at the exchange rate as of the end of the year. Non-monetary items denominated in foreign currency and measured at historical cost, are translated using the exchange rate as of the transaction date. Exchange rate differences arising from translation into the functional currency are recognized on the statement of operations as financial expenses.

C. Financial instruments

1. Non-Derivative financial instruments

a. Non-derivative financial assets

Initial recognition and measurement of financial assets

The Group initially recognizes trade receivables and debt instruments issued on the date that they are created. All other financial assets are recognized initially on the trade date at which the Group becomes a party to the contractual provisions of the instrument. A financial asset is initially measured at fair value plus transaction costs that are directly attributable to the acquisition or issuance of the financial asset. A trade receivable without a significant financing component is initially measured at the transaction price. Receivables originating from contract assets are initially measured at the carrying amount of the contract assets on the date classification was changed from contract asset to receivables.

Derecognition of financial assets

Financial assets are derecognized when the contractual rights of the Group to the cash flows from the asset expire, or the Group transfers the rights to receive the contractual cash flows on the financial asset in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred. When the Group retains substantially all of the risks and rewards of ownership of the financial asset, it continues to recognize the financial asset.

Classification of financial assets into categories and the accounting treatment of each category

Financial assets are classified at initial recognition to one of the following measurement categories: assets at amortized cost; assets at fair value through other comprehensive income – investments in debt instruments; assets at fair value through other comprehensive income – investments in equity instruments; or assets at fair value through profit or loss.

Financial assets are not reclassified in subsequent periods unless, and only if, the Group changes its business model for the management of financial debt assets, in which case the affected financial debt assets are reclassified at the beginning of the period following the change in the business model.

b. Non-derivative financial liabilities

Non-derivative financial liabilities include: accounts payables and other payables.

Initial recognition of financial liabilities

The Group initially recognizes debt securities issued on the date that they originated. All other financial liabilities are recognized initially on the trade date at which the Group becomes a party to the contractual provisions of the instrument.

Note 3 - Significant Accounting Policies (Cont'd)

Subsequent measurement of financial liabilities

Financial liabilities (other than financial liabilities at fair value through profit or loss) are recognized initially at fair value less any directly attributable transaction costs. Subsequent to initial recognition these financial liabilities are measured at amortized cost using the effective interest method. Financial liabilities are designated at fair value through profit or loss if the Group manages such liabilities and their performance is assessed based on their fair value in accordance with the Group's documented risk management strategy, providing that the designation is intended to prevent an accounting mismatch, or the liability is a combined instrument including an embedded derivative.

Derecognition of financial liabilities

Financial liabilities are derecognized when the obligation of the Group, as specified in the agreement, expires or when it is discharged, cancelled or transferred to equity.

c. Derivative financial liabilities

The Group holds derivative financial instruments that do not serve for hedging purposes.

Measurement of derivative financial instruments

Derivatives are recognized initially at fair value; attributable transaction costs are recognized in profit or loss as incurred. Subsequent to initial recognition, derivatives are measured at fair value, and changes therein are accounted for as described below.

The changes in fair value of these derivatives are recognized in profit or loss, as financing income or expense. The fair value of these derivatives is based on an evaluation, and classified as level 3.

D. Intangible assets

1. Research and development

Expenditure on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is recognized in profit or loss when incurred.

Development activities involve also plans or designs for the production of new or substantially improved products and processes. Development expenditure are capitalized only if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Group has the intention and sufficient resources to complete development and to use or sell the asset. Currently all development costs are recognized in profit and loss as expense.

2. Other intangible assets

Other intangible assets, including in-process research and development in respect of the Company's acquisition of TyrNovo and Famewave (see also Note 5), which have infinite useful lives, are measured at cost less accumulated impairment losses.

3. Amortization

The Group examines the useful life of an intangible asset that is not periodically amortized at least once a year in order to determine whether events and circumstances continue to support the decision that the intangible asset has an indefinite useful life.

Notes to the Consolidated Financial Statements

Note 3 - Significant Accounting Policies (Cont'd)

4. Timing of impairment testing

Once a year and on the same date, or more frequently if there are indications of impairment, the Group estimates the recoverable amount of each cash generating unit that contains goodwill, or intangible assets that have indefinite useful lives or are unavailable for use.

E. Loss per share

The Group presents basic and diluted loss per share data for its ordinary share capital. Basic loss per share is calculated by dividing the loss attributable to holders of ordinary shares, by the weighted average number of ordinary shares outstanding during the period.

Diluted loss per share is determined by adjusting the profit or loss attributable to ordinary shareholders of the Company and the weighted average number of ordinary shares outstanding, after adjustment for treasury shares, for the effects of all dilutive potential ordinary shares, which comprise convertible debentures, share options and share options granted to employees.

F. Employee benefits

The Group has a number of post-employment benefit plans. The plans are usually financed by deposits with insurance and pension companies, and they are classified as defined contribution plans and as defined benefit plans.

A defined contribution plan is a post-employment benefit plan under which an entity pays fixed contributions into a separate entity and has no legal or constructive obligation to pay further amounts. Obligations for contributions to defined contribution plans are recognized as an expense in profit or loss in the periods during which related services are rendered by employees.

Other long-term employee benefits

The Group's net obligation in respect of long-term employee benefits plans is calculated separately for each plan by estimating the amount of future benefit that employees have earned in the current and prior periods, discounting that amount and deducting the fair value of any plan assets.

G. Share-based payment transactions

The grant-date fair value of equity-settled share-based payment arrangements granted to employees is generally recognized as an expense, with a corresponding increase in equity, over the vesting period of the awards. The amount recognized as an expense is adjusted to reflect the number of awards for which the related service and non-market performance conditions are expected to be met, such that the amount ultimately recognized is based on the number of awards that meet the related service and non-market performance conditions at the vesting date.

H. Provisions

A provision is recognized if, as a result of a past event, the Group has a present legal or constructive obligation that can be estimated reliably, and it is probable that an outflow of economic benefits will be required to settle the obligation.

I. Revenue

The Group recognizes revenue from upfront and milestone payments at the point in time the milestone criteria is met and collectability is probable. The revenue is measured according to the amount of the consideration to which the Group expects to be entitled.

Notes to the Consolidated Financial Statements

Note 3 - Significant Accounting Policies (Cont'd)

Identifying the contract

The Group accounts for a contract with a customer only when the following conditions are met:

(a) The parties to the contract have approved the contract (in writing, orally or according to other customary business practices) and they are committed to satisfying the obligations attributable to them;

(b) The Group can identify the rights of each party in relation to the goods or services that will be transferred;

(c) The Group can identify the payment terms for the goods or services that will be transferred;

(d) The contract has a commercial substance (i.e. the risk, timing and amount of the entity's future cash flows are expected to change as a result of the contract); and

(e) It is probable that the consideration, to which the Group is entitled to in exchange for the goods or services transferred to the customer, will be collected.

For the purpose of section (e) the Group 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 Group 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.

Identifying performance obligations

On the contract's inception date, the Group assesses the goods or services promised in the contract with the customer and identifies as a performance obligation any promise to transfer to the customer one of the following:

(a) Goods or services (or a bundle of goods or services) that are distinct; or

(b) A series of distinct goods or services that are substantially the same and have the same pattern of transfer to the customer.

The Group identifies goods or services promised to the customer as being distinct when the customer can benefit from the goods or services on their own or in conjunction with other readily available resources and the Group's promise to transfer the goods or services 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 Group 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.

Determining the transaction price

The transaction price is the amount of the consideration to which the Group expects to be entitled in exchange for the license and commercialization agreement. The Group considers the effects of all the following elements when determining the transaction price: variable consideration, the existence of a significant financing component, non-cash consideration, and consideration payable to the customer.

Note 3 - Significant Accounting Policies (Cont'd)

Variable consideration

The transaction price includes fixed amounts and amounts that may change as a result of discounts, refunds, credits, price concessions, incentives, performance bonuses, penalties, claims and disputes and contract modifications that the consideration in their respect has not yet been agreed by the parties.

The Group includes variable consideration, or part of it, 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. At the end of each reporting period and if necessary, the Group revises the amount of the variable consideration included in the transaction price.

Right to use and right to access

To determine whether the Group's promise to grant a license provides a customer with either a right to access the Group's IP or a right-to-use the Group's IP, the Group considers whether a customer can direct the use of, and obtain substantially all of the remaining benefits from, a license at the point in time at which the license is granted.

A license is considered a "right-to-use" license when the customer maintains control of the IP upon its transfer. However, if the grantor of the license maintains involvement with the IP after its transfer, and the customer cannot direct the use of, and obtain substantially all of the remaining benefits from the license, then the license is considered a right-to-access license. The license granted by the Company, which relates to its product is granted to a third party which can obtain direct use of, and substantially all of the remaining benefits from the license at the point in time at which the license is granted. The Group will not continue to be involved in any activities that significantly affect the IP at the specific territory. Therefore recognized the license granted as right-to-use license.

Principal or agent

When another party is involved in providing goods or services to the customer, the Group examines whether the nature of its promise is a performance obligation to provide the defined goods or services itself, which means the Group 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 Group is an agent and therefore recognizes revenue in the amount of the net commission.

The Group engaged with a third party to manufacture its products for the Group's customer ("the Manufacturing Agreement").

The Group is a principal when it controls the promised goods or services before their transfer to the customer. Indicators that the Group controls the goods or services before their transfer to the customer include, inter alia, as follows: the Group is the primary obligor for fulfilling the promises in the contract; the Group has inventory risk before the goods or services are transferred to the customer; and the Group has discretion in setting the prices of the goods or services.

Accordiagly the Company accounts for the manufacturing agreement as an agent on a net basis.

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.

The Group 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.

Notes to the Consolidated Financial Statements

Note 3 - Significant Accounting Policies (Cont'd)

Non-cash consideration

Non-cash consideration is measured at fair value. When the fair value of the consideration cannot be measured reliably, the Group measures the consideration indirectly by reference to the standalone selling price of the goods or services promised to the customer.

Royalties

The Company recognizes revenue for sales-based royalties promised in exchange for a license of intellectual property when the later of the following events occurs: (a) the subsequent sale occurs; or (b) the performance obligation to which some or all of the sales-based royalties has been satisfied. The Company has yet to recognize revenues from royalties.

J. Financing income and expense

Finance income comprises changes in the fair value of the financial liability through profit and loss, and income from short term deposits.

Finance expenses include loss from exchange rate differences and interest fee. Interest expense is recognized, using the effective interest method. In the statements of cash flows, interest received is presented as part of cash flows from investing activities and interest paid is presented as part of cash flows from financing activities.

K. Equity

Incremental costs directly attributable to an expected issuance of an instrument that will be classified as equity are recognized as an asset in deferred expenses in the statement of financial position. The costs are deducted from the equity upon the initial recognition of the equity instruments, or are expensed as financing expenses in the statement of operations when the issuance is no longer expected to take place.

L. Issuance of units of securities

The consideration received from the issuance of units of securities is attributed initially to financial liabilities that are measured each period at fair value through profit or loss, and then to financial liabilities that are measured only upon initial recognition at fair value. The remaining amount is allocated to equity.

Direct issuance costs are attributed to the specific securities in respect of which they were incurred, whereas joint issuance costs are attributed to the securities on a proportionate basis according to the allocation of the consideration from the issuance of the units, as described above.

M. Income tax expense

Income tax comprises current and deferred tax. Current tax and deferred tax are recognized in profit or loss except to the extent that they relate to a business combination, or are recognized directly in equity or in other comprehensive income to the extent they relate to items recognized directly in equity or in other comprehensive income.

Current taxes

Current tax is the expected tax payable (or receivable) on the taxable income for the year, using tax rates enacted or substantively enacted at the reporting date. Current taxes also include taxes in respect of prior years and any tax arising from dividends.

Deferred taxes

A deferred tax asset is recognized for unused tax losses, tax benefits and deductible temporary differences, to the extent that it is probable that future taxable profits will be available against which they can be utilized.

Deferred tax assets that were not recognized are reevaluated at each reporting date and recognized if it has become probable that future taxable profits will be available against which they can be utilized.

Notes to the Consolidated Financial Statements

Note 3 - Significant Accounting Policies (Cont'd)

N. Leases

Policy applicable as from January 1, 2019

Determining whether an arrangement contains a lease

On the inception date of the lease, the Group 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 Group 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.

For lease contracts that contain non-lease components, such as services or maintenance, that are related to a lease component, the Group elected not to separate non-lease components from lease components and instead accounting for all the lease components and related non-lease components as a single lease component.

Leased assets and lease liabilities

Contracts that award the Group control over the use of a leased asset for a period of time in exchange for consideration, are accounted for as leases. Upon initial recognition, the Group recognizes a liability at the present value of the balance of future lease payments (these payments do not include certain variable lease payments), and concurrently recognizes a right-to-use asset at the same amount of the lease liability, adjusted for any prepaid or accrued lease payments, plus initial direct costs incurred in respect of the lease.

Since the interest rate implicit in the Group's leases is not readily determinable, the incremental borrowing rate of the lessee is used. Subsequent to initial recognition, the right-to-use asset is accounted for using the cost model, and depreciated over the shorter of the lease term or useful life of the asset.

The Group has elected to apply the practical expedient by which short-term leases of up to one year and/or leases in which the underlying asset has a low value, are accounted for such that lease payments are recognized in profit or loss on a straight-line basis, over the lease term, without recognizing an asset and/or liability in the statement of financial position.

The lease term

The lease term is the non-cancellable period of the lease plus periods covered by an extension or termination option if it is reasonably certain that the lessee will or will not exercise the option, respectively.

Variable lease payments

Variable lease payments that depend on an index or a rate, are initially measured using the index or rate existing at the commencement of the lease and are included in the measurement of the lease liability. When the cash flows of future lease payments change as the result of a change in an index or a rate, the balance of the liability is adjusted against the right-to-use asset.

Other variable lease payments that are not included in the measurement of the lease liability are recognized in profit or loss in the period in which the event or condition that triggers payment occurs.

Depreciation of right-to-use asset

After lease commencement, a right-to-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:

● Office improvements	2-5 years
● Motor vehicles	2-3 years
● Office equipment	5-10 years

Note 3 - Significant Accounting Policies (Cont'd)

Policy applicable before January 1, 2019

Determining whether an arrangement contains a lease

At inception or upon reassessment of an arrangement, the Group determines whether such an arrangement is or contains a lease. An arrangement is a lease or contains a lease if the following two criteria are met:

- The fulfillment of the arrangement is dependent on the use of a specific asset or assets; and
- The arrangement contains rights to use the asset.

At inception or upon reassessment of the arrangement, the Group separates payments and other consideration required by such an arrangement into those for the lease and those for other elements on the basis of their relative fair values.

If the Group concludes for a finance lease that it is impracticable to separate the payments reliably, an asset and a liability are recognized at an amount equal to the fair value of the underlying asset. Subsequently the liability is reduced as payments are made and an imputed finance charge on the liability is recognized using the buyer's incremental borrowing rate.

Other leases are classified as operating leases, and the leased assets are not recognized on the Group's statement of financial position.

Lease payments

Payments made under operating leases, other than conditional lease payments, are recognized in profit or loss on a straight-line basis over the term of the lease. Lease incentives received are recognized as an integral part of the total lease expense on a straight-line basis, over the term of the lease. Minimum lease payments made under operating leases are recognized in profit or loss as incurred.

O. New standards and interpretations not yet adopted

(1) IAS 1 Presentation of Financial Statements

Amendment to IAS 1, Presentation of Financial Statements: Classification of Liabilities as Current or Non-Current

The Amendment replaces certain classification requirements for current or non-current liabilities. 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. A right is in existence at the end of the reporting period 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, 2022 and is applicable retrospectively, including an amendment to comparative data.

The Group is examining the effects of the Amendment on the consolidated financial statements with no plans for early adoption.

Notes to the Consolidated Financial Statements

Note 3 - Significant Accounting Policies (Cont'd)

(2) Amendment to IAS 37, Provisions, Contingent Liabilities and Contingent Assets

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 Group is examining the effects of the Amendment on the financial statements with no plans for early adoption.

(3) 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 Amendment is effective for annual periods beginning on or after January 1, 2022.

In the opinion of the Group, application of the Amendment may have an effect on the accounting treatment of future acquisitions of operations with no plans for early adoption.

Notes to the Consolidated Financial Statements

Note 4 - Operating Segments

Since 2018 the chief operating decision maker (CODM) has started to review the results of two reportable segments, as described below, which form the Group's strategic business units. The strategic business units offer different products and services and the allocation of resources and evaluation of performance are managed separately because they require different technology and marketing strategies. During 2020, the Group reported to the Chief of Decision Maker (CODM) revenues, research and development expenses and loss before sales, general and administrative expenses for each segment on at least a semi annualy basis. For prior years, amounts were restated consistently with the 2020 reporting. The following summary describes the operations in each of the Group's operating segments:

- Pain and Hypertension – Includes development and marketing of Consensi^{R} a combination drug indicated for treating osteoarthritis pain and hypertension simultaneously, which was approved by the FDA for marketing in the U.S and has partner agreements in the U.S, China and South Korea.

- Oncology – Includes development of therapies to overcome tumor immune evasion and drug resistance in order to create successful long-lasting treatments for people with cancer.

  NT219 and CM24 development activities qualify for aggregation due to the similarities of their long-term economic characteristics, nature of products and services, class of customers and processes for procurement, manufacturing and distribution.

The accounting policies of the operating segments are the same as described in Note 3 regarding significant accounting policies.

Performance is measured based on segment operating results as included in reports that are regularly reviewed by the chief operating decision maker. Segment results are used to measure performance as management believes that such information is the most relevant in evaluating the results of certain segments relative to other entities that operate within these industries. Segment results reported to the chief operating decision maker includes revenue and research and development expenses which are directly attributable to a segment on a reasonable basis.

Information about reportable segments

Information regarding the results of each reportable segment is included below.

	For the year ended December 31, 2020				
	Pain and Hypertension	Oncology	Total reportable segments	Reconciliations (*)	Total consolidated
	USD in thousands				
Revenues	**1,000**	**-**	**1,000**	**-**	**1,000**
Research and development expenses	**265**	**6,466**	**6,731**	**757**	**7,488**
Loss (profit) before sales, general and administrative expenses	**(735)**	**6,466**	**5,731**	**757**	**6,488**
Operating loss					**12,612**
Finance expenses, net					**15,462**
Loss for the year					**28,074**

Notes to the Consolidated Financial Statements

Note 4 - Operating Segments (Cont'd)

	For the year ended December 31, 2019				
	Pain and Hypertension	Oncology	Total reportable segments	Reconciliations (*)	Total consolidated
	USD in thousands				
Revenues	1,000	-	1,000	-	1,000
Research and development expenses	395	2,041	2,436	238	2,674
Loss (profit) before sales, general and administrative expenses	(605)	2,041	1,436	238	1,674
Operating loss					7,156
Finance income, net					(1,479)
Tax Expenses					216
Loss for the year					5,893

	For the year ended December 31, 2018				
	Pain and Hypertension	Oncology	Total reportable segments	Reconciliations (*)	Total consolidated
	USD in thousands				
Revenues	1,000	-	1,000	-	1,000
Research and development expenses	2,185	2,537	4,722	546	5,268
Loss (profit) before sales, general and administrative expenses	1,185	2,537	3,722	546	4,268
Operating loss					7,826
Finance income, net					(2,257)
Loss for the year					5,569

(*) Includes employees share based payments expenses.

Information on geographical segments

In presenting information on the basis of geographical segments, segment revenue is based on the geographical location of customers.

Revenues in 2020 and 2019 are from the U.S and in 2018 from the far-east. For further information see Note 14.

All of the Group's non-current assets are located in Israel.

Notes to the Consolidated Financial Statements

Note 5 - Subsidiaries

For the year ended December 31, 2020	USD thousands
IPR&D related to TyrNovo (see 5A below)	6,172
IPR&D related to Famewave (see 5B below)	14,310
Total intangible assets	20,482

A Acquisition of Tyrnovo

1. On January 13, 2017, the Company completed its acquisition from Goldman Hirsh Partners Ltd ("GHP") of a controlling interest in TyrNovo, a privately-owned Israeli company, which is developing NT219, a small molecule that has demonstrated in pre-clinical studies, the potential to overcome resistance to multiple anti-cancer drugs.

Pursuant to the terms of the transaction, the Company issued to GHP 564,625 of its Ordinary Shares (the "Consideration Shares") and paid GHP aggregate cash proceeds of approximately USD 2 million (the "Cash Consideration") in exchange for 9,570 Ordinary Shares in TyrNovo, that represented approximately 65% of TyrNovo's shares. In addition, the Company was assigned a loan in the amount of USD 101 thousand which had been made by GHP to TyrNovo (the "TyrNovo Acquisition"). USD 167 thousand of the Cash Consideration was held back by the Company pending the fulfillment of certain conditions as agreed to between the Company and GHP. During 2019 the Company and GHP signed an agreement, according to which the Company paid GHP USD 91 thousand and the remaining amount of USD 76 thousand was retained by the Company to cover any future claims it might have with regards of any matter the above amount was withheld for and is waived by GHP. The Company has written off this remaining liability in June 2019.

Acquisition of the Company was accounted for as the acquisition of a group of assets and liabilities in view of the acquired company not being a business and therefore not meeting the definition of a business combination in IFRS 3. Accordingly, the transaction consideration was allocated proportionately to the identifiable assets and liabilities acquired, based on their fair value at the acquisition date. In addition, no goodwill was recognized and no deferred taxes were recognized in respect of the temporary difference that existed on the acquisition date.

(1) Consideration

The following summarizes the acquisition date fair value of each major class of consideration:

	USD thousands
Cash	2,000
Equity instruments issued (564,625 Ordinary Shares) (1)	1,800
Assignment of loan to the Company	(101)
Total consideration transferred	3,699

(1) The fair value of the Ordinary Shares issued was based on the listed share price of the Group on January 11, 2017 of approximately USD 3.19 per share.

Note 5 - Subsidiaries (Cont'd)

(2) Identifiable assets acquired and liabilities assumed

The following table summarizes the recognized amounts of assets acquired and liabilities assumed at the date of acquisition:

	USD thousands
Current assets	21
Fixed assets, net	3
Intangible assets (2)	6,172
Short-term credit from bank	(16)
Trade payables	(123)
Other payables	(212)
Long-term related parties	(130)
Total net identifiable assets	5,715

(2) In-process research and development

Purchased in-process research and development expense represents the value assigned to research and development projects, which were commenced but not yet completed at the date of acquisition. Technological feasibility for these projects has not been established and they have no alternative future use in research and development activities or otherwise.

2. Additional acquisition of minority shareholders

In October 2017, the Company signed an agreement for the acquisition of an additional 27% stake in TyrNovo (the "Newly Acquired TyrNovo Shares"), from a group of unaffiliated minority shareholders of TyrNovo, who collectively held 4,024 ordinary shares, or approximately 27%, of TyrNovo. In exchange for these Newly Acquired TyrNovo Shares, the Company issued to these unaffiliated minority shareholders of TyrNovo, in aggregate, 658,484 newly issued ordinary shares of the Company, which, at that time, represented approximately 6% of the Company's issued and outstanding share capital**.**

The closing of this transaction took place on March 15, 2018, following which the Company held approximately 91.9% of TyrNovo's issued and outstanding ordinary shares.

The carrying amount of TyrNovo's net assets in the consolidated financial statements on the date of the acquisition was USD 2,821 thousand. The Group recognized a decrease in non-controlling interests of USD 768 thousand, an increase in share premium of USD 1,483 thousand and a decrease in a capital reserve for transactions with non-controlling interest of USD 715 thousand.

3. Settlement with a minority shareholder

In June 2018, the Company signed an agreement with a minority shareholder in TyrNovo, Taoz, for the acquisition of its holding in TyrNovo, which was approximately 4.1% of TyrNovo's share capital. In exchange for these shares and for the waiving of investment rights and put options which were granted on February 9, 2017, the Company issued to Taoz 140,845 newly issued ordinary shares of the Company. The fair value of the shares issued as consideration for the acquisition of TyrNovo Shares amounted to USD 237 thousand. The fair value of the shares issued in consideration for waving the rights amounted to USD 136 thousand. As part of the agreement, the Company committed to register the newly issued shares for trading. The registration statement, registering the Company's ADSs representing the newly issued shares for trading, was declared effective by the SEC as of August 8, 2018. In accordance with the agreement, the Company paid to Taoz in cash the difference between the share price of Purple's shares on the closing date to that on the registration date, which amounted to USD 160 thousand. The cash payment was recorded to finance expenses.

The carrying amount of TyrNovo's net assets in the consolidated financial statements on the date of the acquisition was USD 1,977 thousand. The Group recognized a decrease in non-controlling interests of USD 93 thousand, an increase in share premium of USD 237 thousand and a decrease in a capital reserve for transactions with non-controlling interest of USD 144 thousand.

Note 5 - Subsidiaries (Cont'd)

In addition, the Company derecognized the derivative liability of USD 1,030 thousand, recognized an amount of USD 894 thousand as other income and an increase in share premium of USD 136 thousand deriving from the waiving of the rights, as described above.

The closing of this transaction took place on June 15, 2018, following which the Company held approximately 97.4% of TyrNovo's issued and outstanding ordinary shares.

4. Non-controlling interests

Non-controlling interests are presented based on their proportionate interest in the recognized amount of the assets and liabilities of TyrNovo, see Note 10F.

5. During 2019 TyrNovo issued 13,750 shares to Purple which increased the Company's direct ownership of equity from 97.6% to 98.47%.

B. Acquisition of Famewave

On March 14, 2019 the Company signed an agreement to acquire 100% of FameWave Ltd, a privately held biopharmaceutical Company developing CM24, ("FameWave") from its shareholders in exchange for USD 10 million worth of its newly issued ADSs with a long-term lock-up period, priced at USD 12.3 per ADS, plus 50% warrant coverage based on an exercise price of USD 19.8 per ADS with a 4-year term. In addition, the Company provided a loan to FameWave of up to approximately USD 2 million to finance its operation until the closing of the acquisition. The acquisition closed on January 7, 2020.

In consideration of the transfer of the FameWave shares to the Company and completion of the other condition set forth in the acquisition agreement, the aggregate purchase price paid by the Company for 100% of shareholders, and other stake holders (a) 807,561 of the Company's ADSs, (b) warrants to purchase 403,781 additional ADSs with a term of exercise of 4 years beginning on the date of issuance, and subject to other terms and conditions as set forth herein and in the 'warrant agreements of the Company (c) 54,472 RSUs and 27,236 options to purchase 27,236 shares of the Company.

The consideration was recorded based on the fair value of the assets purchased.

Under the terms of the agreement, OrbiMed, Pontifax and Arkin Holdings, leading life-science focused investment funds, exchanged their shares in FameWave for Purple ADSs and warrants, and invested USD 3.5 million in Purple in exchange for additional 284,553 newly issued ADSs of Purple. As of January 7, 2020, OrbiMed, Pontifax and Arkin Holdings each held approximately 11% of Purple's shares on a non-diluted basis.

The acquisition was accounted for as an asset purchase as it does not meet the definition of a business combination in accordance with IFRS 3.

FameWave does not include a system of inputs and processes, and at this stage there are no outputs. In addition, most of the fair value of the acquired assets is attributable to a single identifiable asset which is the in-process research and development asset. In addition, no goodwill was recognized on the acquisition date, See below.

Notes to the Consolidated Financial Statements

Note 5 - Subsidiaries (Cont'd)

Identifiable assets acquired and liabilities assumed

The following table summarizes the recognized amounts of assets acquired and liabilities assumed at the date of acquisition:

	USD thousands
Cash	69
Intangible assets (1)	14,310
Other receivables	6
Trade payables	(2,283)
Other payables	(2,102)
Total net identifiable assets	10,000

(1) In-process research and development

Purchased in-process research and development expense represents the value assigned to research and development projects, which were commenced but not yet completed at the date of acquisition. Technological feasibility for these projects has not been established and they have no alternative future use in research and development activities or otherwise.

The fair value of the assets and liabilities recognized at the acquisition date was determined according to the estimated fair value of those items. The fair value was estimated as the amount for which those items could be acquired or sold between a willing buyer and a willing seller in an arm's length transaction.

C. The recoverable amount of the in-process research and development assets (hereinafter – "intangible assets") was based on their value in use and was determined by discounting the future cash flows to be generated from them by using the discounted cash flows method, on the annual year test. The recoverable amount of the intangible assets exceeds their carrying amount, thus no impairment loss was recognized. The discount rate used for calculating intangible assets recoverable amount is 15%, in addition to taking into consideration the risks associated in drug candidates at this stage of development.

Notes to the Consolidated Financial Statements

Note 6 - Cash and Cash Equivalents

	As of December 31	
	2020	2019
	USD thousands	
Balance in USD	**10,758**	4,279
Balance in other currencies	**489**	106
Total cash and cash equivalents	**11,247**	4,385

Note 7 – Leases

The Group applies IFRS 16, *Leases*, as from January 1, 2019. The Group has lease agreements with respect to offices.

1. Information regarding material lease agreements entered into during the period

The Group entered into an agreement for the lease of offices in Rehovot as from September 15, 2020. Accordingly, the Group recognized in the statement of financial position a right-to-use asset in the amount of USD 817 thousand concurrently with the recognition of a lease liability in the same amount. The agreement has an option to extend the lease, for additional 5 years. This additional period is not considered in the calculation of the liability as the Group currently does not predict it will use this option. The potential future lease payments not included in the lease liability are USD 534 thousand.

2. Right-to-use assets

Carrying amounts of right-to-use assets and movement during the period:

	Office Lease
	USD thousands
Balance as at January 1, 2019	0
Depreciation on right-to-use assets	(194)
Change during the year	400
Balance as at December 31, 2019	206
Balance as at January 1, 2020	**206**
Depreciation on right-to-use assets	**(233)**
Change during the year	**817**
Balance as at December 31, 2020	**790**

Notes to the Consolidated Financial Statements

Note 7 - Leases (Cont'd)

3. Lease liability

Maturity analysis of the Group's lease liabilities

	December 31, 2020
	USD thousands
Less than one year	**210**
One to five years	**840**
Total	**1,050**
Short-term lease liability	**207**
Long-term lease liability	**688**

4. Additional information on leases

(a) Amounts recognized in profit or loss

	2020	2019
	USD thousands	USD thousands
Interest expenses on lease liability	**41**	45

	2018
	USD thousands
Lease payments recognized as an expense	209

Note 8 - Other Current Assets

	As of December 31	
	2020	2019
	USD thousands	
Receivables	-	1,493
Government authorities	**197**	182
Prepaid expenses and other receivables	**780**	232
Total other current assets	**977**	1,907

Note 9 - Other Payables

	As of December 31	
	2020	2019
	USD thousands	
Contract liabilities, see Note 14	-	961
Due to related parties - payroll related	**541**	587
Accrued expenses	**880**	255
Government authorities	**43**	36
Payroll related	**229**	267
	1,693	2,106

Notes to the Consolidated Financial Statements

Note 10 - Equity

A. The Company's authorized share capital is 1,000,000,000 ordinary shares, with no par value, and 50,000,000 non-voting senior preferred shares, with no par value, divided into 5 classes of 10,000,000 preferred shares in each class.

On August 6, 2020 in an extraordinary shareholders' meeting, it was resolved to increase the Company's registered and authorized ordinary share capital to 1,000,000,000 ordinary shares, no par value. On August 21, 2020 the ratio between ADSs and shares was changed from 1:1 to 1:10 (each 1 ADS equals 10 shares). The following note was adjusted to reflect this change and all share data is presented in ADS equivalents.

In these consolidated financial statements, all numbers of ADSs reflect the reverse share split and ADS ratio change retrospectively.

B. The Company's share capital

	As of December 31, 2020		As of December 31, 2019	
	Number of shares in thousands			
	Authorized	Issued and paid-in	Authorized	Issued and paid-in
Shares, no par value	**1,000,000**	**172,106**	250,000	19,564
Class A preferred shares, no par value	**10,000**	**-**	10,000	-
Class B preferred shares, no par value	**10,000**	**-**	10,000	-
Class C preferred shares, no par value	**10,000**	**-**	10,000	-
Class D preferred shares, no par value	**10,000**	**-**	10,000	-
Class E preferred shares, no par value	**10,000**	-	10,000	-

C. Changes in share capital during the year

	For the year ended December 31		
	2020	2019(*)	2018(*)
	Number of ADSs in thousands		
Issued as at January 1	**1,956**	1,600	1,122
Issuance of ADSs (See D below)	**8,573**	343	326
Issuance of shares (See Note 5)	**-**	-	80
Vesting of RSUs	**7**	10	12
Exercise of warrants	**6,675**	3	61
Issued as at December 31	**17,211**	1,956	1,601

(*) Restated to reflect a 1:10 reverse ratio of the ADSs, that took place in August 2020.

D. Financing rounds

1. On June 25, 2020, in a registered direct offering on the NASDAQ, the Company raised USD 35 million gross (approximately USD 30.7 million net of placement agent fees including non- cash fees and other offering related expenses). In this registered direct offering, the Company issued an aggregate of 3,888,889 ADSs at a purchase price of USD 9 per ADS that were recorded in equity in the amount of USD 19,201 thousand net of issuance expenses. The Company also agreed to issue to the investors registered warrants to purchase up to an aggregate of 1,944,444 ADSs (hereinafter the "June 2020 warrants") that were recorded in receipts on account of warrants at a value of USD 11,472 thousand net of issuance expenses. The registered June 2020 warrants have a term of 5 years and are exercisable immediately and have an exercise price of USD 9 per ADS.

   In addition, the Company issued to the placement agent (or its designees) registered compensation warrants to purchase up to 194,443 ADSs at a value of USD 1,199 thousand which is included in the net amount raised above, at an exercise price of USD 11.25 per ADS. The registered placement agent warrants are immediately exercisable and have a term of 5 years from the date of the effective date of the offering.

   In addition to the 2,000,000 warrants that were exercised as mentioned below there were 4,675,000 warrants that were exercised during the period.

   On May 8, 2020, in a registered direct offering on the NASDAQ, the Company raised USD 10 million gross (approximately USD 8.4 million net of placement agent fees including non- cash fees and other offering related expenses). In this registered direct offering, the Company issued an aggregate of 2,500,000 ADSs at a purchase price of USD 4 per ADS that were recorded in equity in the amount of USD 709 thousand net of issuance expenses. The Company issued to the investors unregistered warrants to purchase up to an aggregate of 2,500,000 ADSs (hereinafter the "May 2020 warrants"). These May 2020 warrants have a term of 5.5 years, are exercisable immediately and have an exercise price of USD 4 per ADS.

   The warrants were considered a derivative instrument (due to a cashless exercise feature), and were recorded as a liability in the amount of USD 9,157 thousand. On July 17, 2020 the warrants were listed for trading, and, as a result the cashless feature expired. Therefore, the Company reclassified the warrants to equity according to the warrants fair value on the listing date. The changes in the warrants fair value was recorded as financial expenses. The warrants fair value on the listing date was USD 16,403 thousand.

   In addition, the Company issued to the placement agent (or its designees) compensation warrants to purchase up to 175,000 ADSs at a value of USD 559 thousand which is included in the net amount raised above, at an exercise price of USD 5 per ADS. The placement agent warrants are immediately exercisable and have a term of 5 years from the date of the effective date of the offering.

   On April 19, 2020, the Company entered into warrant exercise letters, with certain institutional investors holding the March 2020 warrants (as detailed below) to purchase an aggregate of up to 2 million of the Company's ADSs, at an exercise price of USD 3.25 per ADS. The holders agreed to exercise their March 2020 warrants in full, for gross proceeds of approximately USD 6.5 million (approximately USD 5.4 million net of placement agent fees including non- cash fees and other offering related expenses). In exchange for exercising the warrants the Company issued an aggregate of 2 million ADS, that were recorded in equity in the amount of USD 3,170 thousand.

   Under the exercise agreement, the Company also issued to the holders, in a private placement, new unregistered warrants to purchase up to an aggregate of 2.2 million ADSs at an exercise price of USD 3.25 per ADS (hereinafter the "new April 2020 warrants"). The new April 2020 warrants were exercisable immediately and had an exercise period of 5.5 years from the date of the issuance.

Note 10 - Equity (Cont'd)

The warrants were considered a derivative instrument (due to a cashless exercise feature) and were recorded as a liability in the amount of USD 5,283 thousand. On May 20, 2020 the warrants were listed for trading, and, as a result the cashless feature expired. Therefore, the Company reclassified the warrants to equity according to the warrants fair value on the listing date. The changes in the warrants fair value was recorded as financial expenses. The warrants fair value on the listing date was USD 10,982 thousand.

The change in the fair value of these derivative instruments is primarily due to the change in the Company's share price between April 19, 2020 and May 20, 2020 which is reflected in the expected volatility.

In addition, the Company issued to the placement agent (or its designees) warrants to purchase up to 140,000 ADSs at a value of USD 315 thousand which is included in the net amount raised above, which have the same terms as the new April 2020 warrants except for an exercise price of USD 4.0625 per ADS.

On March 16, 2020, in a public offering on the NASDAQ, the Company raised USD 6 million gross (approximately USD 4.6 million net of placement agent fees including non- cash fees and other offering related expenses). In this public offering, the Company issued an aggregate of 962,000 ADS that were recorded in equity in the amount of USD1,674 thousand gross and 1,038,000 pre-funded warrants which were immediately exercised (an exercise price of USD 0.001 per each ADS) that were recorded in receipts on account of warrants in the amount of USD 1,806 thousand gross, and warrants to purchase an aggregate of up to 2,000,000 (hereinafter the "March 2020 warrants") that were recorded in receipts on account of warrants in the amount of USD 2,520 thousand gross. The March 2020 warrants were exercisable at an exercise price of USD 3.25 per ADS and had a term of exercise period of 5 years from the date of the issuance.

In addition, the Company issued to the placement agent (or its designees) warrants to purchase up to 140,000 ADSs at a value of USD 241 thousand which is included in the net amount raised above. The placement agent warrants are exercisable at an exercise price of USD 3.75 per ADS and will terminate on March 12, 2025.

129,861 ADSs were issued in connection with the 2020 transactions to a former placement agent and its cost is included in the net amounts raised above.

See note 5 for additional ADS and warrants issued during the period.

2. In January 2019, in a registered direct offering on the NASDAQ, the Company raised USD 6 million gross (approximately USD 5.1 million net of placement agent fees and other offering related expenses). Part of the issuance expenses were warrants issued to the placement agent in the amount of USD 298 thousand were recorded in equity. USD 129 thousand were recorded net of share premium and USD 169 thousand were recorded to finance expense.

   In this registered direct offering, the Company issued 342,857 ADSs and, in a concurrent private placement, 257,143 non-listed warrants to purchase 257,143 ADSs. Each non-listed warrant is exercisable until July 15, 2024 at an exercise price of USD 20.00 per ADS.

   The ADSs issued were recorded in equity in an amount of USD 2,200 thousand, net of issuance expenses. The warrants were considered a derivative instrument (due to a cashless exercise feature), and were recorded as a liability in the amount of USD 3,406 thousand. Issuance expenses related to the warrants, in the amount of USD 515 thousand were recorded to finance expense. During September 2019, the warrants were listed for trading, and as a result the cashless feature expired. Therefore, the Company reclassified the warrants to equity according to the warrants fair value on the listing date. The change in the warrants fair value was recorded as financial income. The warrants fair value on the listing date was USD 1,273 thousand. See also Note 21B.

3. In June 2018, in a registered direct offering on the NASDAQ, the Company raised a gross amount of USD 8.1 million (approximately USD 7.4 million net of placement agent fees and other offering related expenses).

   In this registered direct offering, the Company issued 326,000 ADSs and, in a concurrent private placement, 163,000 non-listed warrants to purchase 163,000 ADSs. Each non-listed warrant is exercisable until December 5, 2023 at an exercise price of USD 28. 0 per ADS. The ADS's issued were recorded in equity in an amount of USD 4,276 thousand, net of issuance expenses. The warrants were considered a derivative instrument (due to a cashless exercise feature) and were recorded as a liability in the amount of USD 3,467 thousand. Issuance expenses related to the warrants, in the amount of USD 301 thousand were recorded to finance expenses.

   During September 2019, the warrants were listed for trading, as a result the cashless feature expired. Therefore, the Company reclassified the warrants to equity according to the warrants fair value on the listing date. The changes in the warrants fair value was recorded as financial income. The warrants fair value on the listing date was USD 661 thousand. See also Note 21B.

E. Other equity transactions

1. During 2020, the Company issued 11 thousand ordinary shares on account of vested RSUs granted in 2017 and 2018 and 54 thousand fully vested RSUs were granted to an officer, See also Note 11A.

2. During 2020, 6,675 thousand warrants, issued in March- June 2020, were exercised into 56,366 thousand ordinary shares. Subsequently, an amount of USD 23,780 thousand was recorded to share premium against receipts on accounts of warrants.

3. During 2020 the Company acquired 100% of FameWave Ltd for the equity details, See Note 5B.

4. During 2019, the Company issued 97 thousand ordinary shares on account of vested RSUs granted in 2017 and 2018. See also Note 11A.

5. During 2019, 29 thousand warrants, issued in July 2017, were exercised into 29 thousand shares for a consideration of USD 43 thousand. Subsequently, an amount of USD 42 thousand was recorded to share premium against receipts on accounts of warrants.

6. During 2018, 343 thousand warrants, issued in July 2017, were exercised into 343 thousand shares for a consideration of USD 515 thousand. In addition, 484 thousand warrants, issued in July 2017, were exercised into 264 thousand shares on a cashless exercise, and an amount of USD 1,618 thousand was recorded to share premium against derivative liabilities.

7. During 2018, the Company issued 121 thousand ordinary shares on account of vested RSUs granted in 2017. See also Note 11A.

F. Non-controlling interests

The following table summarizes the information relating to a subsidiary that has non-controlling interests, before any intra-group eliminations:

TyrNovo Ltd.	December 31 2020	December 31 2019
	in USD thousand	
Non-controlling interests percentage	**1.53%**	1.53%
Non-current assets	**16**	24
Current assets	**174**	192
Current liabilities	**(5,543)**	(646)
Net assets	**(5,353)**	(430)
Net assets attributable to non-controlling interests	**(82)**	(7)
Loss for the year	**4,922**	2,847
Loss allocated to non-controlling interests	**75**	43

Notes to the Consolidated Financial Statements

Note 11 - Share-based Payment Arrangements

A. On October 12, 2020, the board of directors of the Company granted 232 thousand options and 232 thousand RSUs to new officer and employees. The options have an exercise price of USD 0.432 per one ordinary share. The options and RSUs will vest over 3 years from the date of grant. The options are exercisable for 5 years from grant date. The fair value of these options and RSUs as of the grant date was measured at USD 171 thousand.

On May 18, 2020, the board of directors of the Company granted 1,853 thousand options and 1,853 thousand RSUs to officers and employees. The options have an exercise price of USD 0.421 per one ordinary share. The options and RSUs will vest over 3 years from the date of grant. The options are exercisable for 5 years from grant date. The fair value of these options and RSUs as of the grant date was measured at USD 1,845 thousand.

In addition, the board of directors of the Company granted a total of 1,463 thousand options and 1,463 thousand RSUs to the Chief Executive Officer, Chairman of the Board of Directors and the other directors.

This grant was approved by the shareholders in August 2020. The options have an exercise price of USD 0.421 per one ordinary share. The options and RSUs will vest over 3 years from the date of grant. The options are exercisable for 5 years from grant date. The fair value of these options and RSUs as of the grant date was measured at USD 2,342 thousand.

On April 2, 2020, the Company granted 178 thousand options to an officer. 151 thousand options have an exercise price of USD 0.347 per one ordinary share, and will vest over 3 years from the grant date. The options are exercisable for 7 years from grant date. The fair value of these options as of the grant date was measured at USD 40 thousand. An additional 27 thousand options were granted that have an exercise price of USD 1.98 per one ordinary share, and will vest over 3 years from the grant date. The options are exercisable for 4 years from grant date. The fair value of these options as of the grant date was measured at USD 3 thousand. In addition, 54,472 RSUs were granted which are fully vested, See Note 5B.

On December 18, 2019, the Company granted 335 thousand options to an officer. The options have an exercise price of USD 0.79 per one ordinary share, and will vest over 3 years from the grant date. The options are exercisable for 7 years from grant date. The fair value of these options as of the grant date was measured at USD 221 thousand.

On December 23, 2019, the Company granted 400 thousand options to the Chairman of the Board. The options have an exercise price of USD 0.814 per one ordinary share, and will vest during 3 years from the grant date. The options are exercisable for 7 years from grant date. This grant was approved by the shareholders in December 2019.

The fair value of these options as of the grant date was measured at USD 207 thousand.

During March and April 2019, the board of directors of the Company approved the grant of 3,162 thousand options to directors, officers, employees and consultants. The options have an exercise price of USD 1.28 – 1.64 per one ordinary share, and will vest during 3 years from the date of grant. The options are exercisable for 5-7 years from grant date. The fair value of these options as of the grant date was measured at USD 2,677 thousand. Those options that were granted to directors were approved by the shareholders of the Company in April 2019.

In addition, the Company granted 61 thousand options to Tmura, an Israeli charity organization, the options have an exercise price equals USD 6 per ordinary share, and were immediately vested at the date of grant. The fair value of these options as of the grant date was measured at USD 56 thousand.

On November 20, 2018, the Company granted 159,759 options and 59,720 RSUs to two officers. The RSUs and options have a vesting period of 3 years from the commencement of the offeree's engagement with the Group, with a one-year cliff for the first one-third of the vested amount, and over 8 quarters thereafter. The exercise period is 5 years from the date of the grant. The options shall have an exercise price equals to USD 1.59 per one ordinary share. 34,825 RSUs were fully vested at the time of the grant. The fair value of these RSUs and options at the date of the grant was measured at USD 71 thousand and USD 127 thousand, respectively.

The Company recorded in 2020 an expense of USD 2,645 thousand (2019 - USD 1,273 thousand, 2018- USD 719 thousand), of which USD 2,409 thousand (2019 - USD 988 thousand, 2018 - USD 660 thousand) are to officers and directors.

Notes to the Consolidated Financial Statements

Note 11 - Share-based Payment Arrangements (Cont'd)

B. The number and weighted average exercise prices (in USD) of share options are as follows:

	Weighted average exercise price			Number of options		
	2020	**2019**	**2018**	**2020**	**2019**	**2018**
Outstanding on January 1	**1.71**	2.6	3.08	**4,754,676**	1,131,781	1,002,022
Expired and forfeited during the year	**0.23**	-	7	**1,486,125**	-	30,000
Granted during the year	**0.43**	1.32	1.59	**3,725,826**	3,622,895	159,759
Outstanding on December 31	**1.02**	1.71	2.6	**6,994,377**	4,754,676	1,131,781
Exercisable on December 31	**1.54**	3.21	2.95	**1,753,632**	1,093,029	873,344

The exercise price is denominated in NIS and are re-measured using historic exchange rates.

The options outstanding at December 31, 2020 had an exercise price of USD 0.346- USD 6 (2019 - USD 0.81- USD 6, 2018 -USD 1.59 - USD 4.39), and weighted average contractual life of 5.89 years (2019 - 5.56 years, 2018 - 5.29 years).

C. The number of RSUs are as follows:

	Number of RSUs	
	2020	**2019**
Outstanding at January 1	**11,509**	109,419
Granted during the year	**3,601,972**	-
Forfeited during the year	**157,500**	-
Vested during the year	**65,981**	97,910
Outstanding at December 31	**3,390,000**	11,509

D. Options to service providers were measured at the fair value of the service, when available.

The fair value of the Company's share options granted to employees, directors and consultants, where fair value of service was not measurable, was measured using the binominal model, using the fair value of the traded warrants with similar terms, making certain adjustments to reflect the specific terms of the options based on the expected duration.

E. The following assumptions were used**:**

	2020	**2019**	**2018**
Share Price - USD	**0.32 - 0.898**	0.746 - 1.22	1.18
Option price - USD	**0.347 - 1.98**	0.49 - 1.1	0.80
Expected volatility (%)	**95.68 - 107**	99.22 - 113.78	105.77
Expected duration (years)	**4 - 7**	4.61 - 7	4.95
Dividend yield (%)	-	-	-
Risk free rate interest rate (%)	**0.298% - 0.5%**	1.63% - 1.95%	1.41%

Notes to the Consolidated Financial Statements

Note 11 - Share-based Payment Arrangements (Cont'd)

F. On January 3, 2018, TyrNovo granted 1,170 options of TyrNovo to certain employees. The options were fully vested at the date of grant. The exercise period is 7 years from the date of the grant. The options shall have an exercise price equals to USD 0.29 per one ordinary share. The fair value of these options at the date of the grant was measured at USD 431 thousand.

The fair value of these options was measured using the binominal model,

The following assumptions were used**:**

	2018
Share Price - USD	368.39
Option price - USD	369.39
Expected volatility (%)	79.16
Expected duration (years)	7
Dividend yield (%)	-
Risk free rate interest rate (%)	2.4%

In 2018, Tyrnovo recorded a share-based compensation expense of USD 431 thousand, of which USD 402 thousand are to key management personnel.

G. Expenses recognized in the consolidated financial statements:

	For the year ended December 31		
	2020	2019	2018
	USD thousands		
Research and development expenses	**756**	238	546
General and administrative expenses	**1,889**	1,035	227
Total share-based expense recognized	**2,645**	1,273	773

Notes to the Consolidated Financial Statements

Note 12 - Transactions and Balances with Related Parties

In addition to their salaries or fees, the Group also provides non-cash benefits to directors and executive officers, and contributes to a post-employment defined contribution plan on behalf of employees, see Note 8 for the balances.

Certain executive officers are entitled to termination benefits of up to 6 monthly salaries or fees, See Note 19.

Executive officers also participate in the Group's share option programs. For further information, see Note 11 regarding share-based payments.

Expenses of key management personnel:

The Company recorded expenses to executive officers:

	For the year ended December 31		
	2020	**2019**	**2018**
		USD thousands	
Short - term employee benefits	**1,982**	1,776	2,165
Post-employment benefits	**19**	22	16
Share based payments	**1,667**	719	574
	3,668	2,517	2,755

The Company recorded expenses to directors:

	For the year ended December 31		
	2020	**2019**	**2018**
		USD thousands	
Short - term benefits	**306**	339	268
Share based payments	**742**	269	86
	1,048	608	354

Notes to the Consolidated Financial Statements

Note 13 - Commitments and contingent liabilities

A. Commitments

1. TyrNovo, has obligations to the Israel Innovation Authority (hereinafter: "IIA") with respect to grants it received from the IIA in connection with TyrNovo's technology. The requirements and restrictions for such grants are found in the Encouragement of Research, Development and Technological Innovation in Industry Law 5744-1984 and in the IIA's rules and guidelines and the terms of these grants.

In general, a recipient company is obligated to pay the IIA royalties from the revenues generated from the sale of products and related services developed as a result of, a research and development program funded by the IIA (currently a yearly rate of 3% to 6%), up to the aggregate amount of the total grants received by the IIA, plus annual interest. Tyrnovo will not be required to repay the grants if it does not generate revenue.

TyrNovo's technologies were developed, at least in part, with funds from IIA grants, and accordingly is obligated to pay royalties on sales of any of its IIA funded products and related services. As of December 31, 2019, the maximum royalty amount that would be payable by TyrNovo, excluding interest, is approximately NIS 5.5 million (USD 1.6 million), and as of such date, TyrNovo had not paid any royalties to the IIA.

The Group does not recognize a liability for royalties because there is no reasonable assurance, as of the reporting period, that the underlying sales will occur in the future. Therefore, the financial statements do not include a liability for these royalties.

2. TyrNovo has entered into a license agreement (the "License Agreement") with Yissum Research Development company of the Hebrew University of Jerusalem Ltd. (hereafter "Yissum") dated August 15, 2013, as amended. In accordance with the License Agreement, Yissum granted the Company an exclusive license to commercialize, exploit, develop, manufacture, market, import, export, distribute, offer to sell, or sell products, that are derived from Yissum's licensed technology.

In consideration for the grant of the license, the Company shall pay Yissum the following consideration during the term of the license:

(i) Royalties at a rate of three percent (3%) of net sales.

(ii) Sublicense fees at a rate of twelve percent (12%) of sublicense consideration.

In addition, Yissum is entitled to receive an exit fee of 12% of the transaction proceeds in the event of certain pre - defined transactions set forth in the License Agreement.

The consolidated financial statements do not include a liability for royalties or sublicense fees for this license agreement as there is no minimum payments and thus obligation will be recognized when the related sales will occur.

3. FameWave has entered into a a license agreement with Tel Hashomer – Medical Research Infrastructure and Services Ltd. ("THM") and Ramot at Tel Aviv University Ltd. ("Ramot") dated April 16, 2012, which was effective as of May 25, 2010, as subsequently amended (the "THM License Agreement"). Pursuant to the THM License Agreement, THM and Ramot granted the Company a worldwide, royalty-bearing, exclusive license to develop, manufacture, produce, market and sell any biopharmaceutical product and/or diagnostic product using patents and inventions owned by THM and Ramot in connection with uses of the glycoprotein CEACAM1.

In consideration for the license grant, the Company shall pay to THM the following during the term of the license:

i) An annual license fee of $10,000 which is credited towards any royalties to be paid during such year.

Note 13 - Commitments and contingent liabilities (Cont'd)

ii) Royalties of three- and one-half (3.5%) of net sales with respect to Biopharmaceutical Products, and royalties of six- and one-half (6.5%) of net sales with respect to Diagnostic Products.

iii) Sublicense fees at a rate of twenty percent (20%) of sublicense consideration with respect to Biopharmaceutical Products, and sublicense fees at a rate of twelve percent (12%) of sublicense consideration with respect to Diagnostic Products.

The Company has undertaken to pay certain milestone payments upon the completion of certain pre-defined clinical and sales milestones.

In addition, THM (on behalf of the licensors) are entitled to receive an exit fee of up to three- and one-half percent (3.5%) of all consideration received because of or in connection with an exit event (as defined in the THM License Agreement).

Finally, THM also received an assignable warrant to purchase, upon the closing of any IPO of FameWave, ordinary shares of FameWave, at a price equal to a certain percentage of the forecast initial market value of FameWave for each share as was determined, prior to the IPO, for the purpose of the IPO.

In accordance with the THM License Agreement, THM is entitled to appoint an observer to FameWave's board of directors who has all the rights of any other director of FameWave save for the right to vote. To date, THM has not acted on this right.

The consolidated financial statements do not include a liability for royalties or sublicense fees for this license agreement as there is no minimum payments and thus obligation will be recognized when the related sales will occur.

B. Claims

1. In December 2015, a lawsuit and a motion to approve such lawsuit as a class action was filed in the Tel Aviv District Court (Economic Division) against the Company and its directors by shareholders who were holding the Company's Tel Aviv Stock Exchange listed securities before the Company's initial public offering in the United States (the "U.S. IPO") that took place in November 2015, claiming damages for the purported class in the motion totaling NIS 16.4 million (USD 4.3 million) due to the U.S. IPO (the "Motion"). In addition to this amount, the petitioners in the motion are seeking remedies in order to redress discrimination against the purported class owing to the dilution caused by the public offering, including the possibility that the purported class should be awarded from the Company amounts reflecting the losses of the purported class from a possible price increase in our shares following the announcement of the Phase III clinical trial results. The Company delivered its response to the court. A preliminary hearing was held by the court on September 12, 2016 and subsequently the court set a schedule for the submission by the petitioners of a motion for discovery, and any responses to such motion. Additional preliminary hearings were held during 2017. On October 24, 2017 the court issued a ruling to stay proceedings in this matter until January 15, 2018 due to the ongoing ISA Investigation (See Note 13B(3) below). At the request of the ISA, this stay was subsequently extended several times by the court. Following approval of the Enforcement Arrangement in connection with the ISA Investigation (see Note 12B(3)), the stay was lifted. An evidentiary hearing has been scheduled for July 8, 2021.

Note 13 - Commitments and contingent liabilities (Cont'd)

2. On November 8, 2016, a shareholder of the Company submitted a request to the court in connection with the Motion to be excluded from the purported class, claiming to have independent causes of action and damages of approximately NIS 1 million (USD 311,042) (the "Petition to Exclude"). The Company responded to the court and, amongst other arguments, the Company noted that pursuant to the Class Action Lawsuits Law 5766-2006 and the Regulations enacted thereunder, at the current stage of the court proceedings with respect to the 2015 Motion such shareholder cannot petition to be excluded from the purported class. The court ordered the shareholder to respond and he has done so. In May 2018, the shareholder filed an independent lawsuit against the Company in the Haifa Magistrates Court seeking damages of approximately NIS 1.1 million (USD 342,146) (the "Separate Lawsuit"). In August 2018, the Haifa Magistrates Court transferred the Separate Lawsuit to the Tel Aviv Magistrates Court. The Company is of the view that such shareholder's claims are identical to the asserted claims for damages in the Motion, and has notified the court of such and has sought a stay of proceedings pending the outcome of the Motion. A preliminary hearing on the Company's motion to dismiss the Separate Lawsuit and/or stay the proceedings was held in May, 2019, at which the court dismissed the claim without prejudice. This shareholder subsequently filed a new separate claim against the Company in the Haifa District Court – Economic Division, which has since been transferred to the Tel Aviv District Court – Economic Division. In January 2020, the Tel Aviv District Court – Economic Division accepted the Company's position that the shareholder's claims are identical to the asserted claims for damages in the Motion, and entered a stay of proceedings pending the outcome of the Motion.

   The Company rejects the claims asserted in the Motion as well as in the Petition to Exclude and the Separate Lawsuit, and, in consultation with its legal advisors, believes that the likelihood of the Company not incurring any financial obligation as a result of this class action exceeds the likelihood that the Company will incur a financial obligation. Therefore, no provision for this matter was recorded in these financial statements.

3. In February 2017 the Company announced that the Israeli Securities Authority (the "ISA") has begun a formal investigation into, amongst other matters, the Company's public disclosures around certain aspects of the studies related to its therapeutic candidate, Consensi.

   In February 2017, four lawsuits and motions to approve the lawsuits as a class action lawsuit (each, a "Motion"), were filed against the Company and certain of its office holders at the Tel Aviv District Court (Economic Division), with each Motion relating to the ISA Investigation (the "2017 Motions"). One of these motions was subsequently withdrawn. The petitioners in one of the motions petitioned the court to dismiss the other two of the 2017 Motions ("Petition for Dismissal"). On December 19, 2017 the court granted the Petition for Dismissal and dismissed the other remaining 2017 Motions. The remaining motion (the "Surviving Motion") was filed against the Company, the Company's executive directors and certain of its present and former directors, by certain shareholders who are requesting to act as representatives of all shareholders of record from December 10, 2015 until February 6, 2017. The plaintiffs allege, among other things, that the Company included misleading information in its public filings which caused the class for which the plaintiffs are seeking recognition an aggregate loss of approximately NIS 29 million (approximately USD 9 million). The court ordered a stay of proceedings due to the then-ongoing ISA Investigation. Following approval of the Enforcement Arrangement in connection with the ISA Investigation, the stay was lifted. On May 29, 2020 the petitioners in the Surviving Motion filed an amended lawsuit and motion to approve the lawsuit as a class action. On November 15, 2020 the respondents filed their responses to the amended motion to approve the lawsuit as a class action. After filling such responses, the court suggested that both parties' resort to mediation, without admitting or accepting the other party's claim. Both parties accepted such suggestion. We expect that the mediation will be commenced shortly.

   The Company rejects the claims in the Surviving Motion. At this preliminary stage the Company is unable, with any degree of certainty, to make any evaluations or any assessments with respect to the Surviving Motion as to the probability of success or the scope of potential exposure, if any. Therefore, no provision for this matter was recorded in these financial statements.

Note 13 - Commitments and contingent liabilities (Cont'd)

4. On February 7, 2017, a holder of the Company's securities listed on the NASDAQ filed in the United States District Court (Southern District of New York) a federal securities class action against the Company, its CEO and former CFO largely relating to the same matters that were the subject of the ISA Investigation. On February 10, 2017, a holder of the Company's securities listed on the NASDAQ filed in the Superior Court of the State of California a securities class action against the Company, its CEO and former CFO and the underwriters in the Company's initial public offering in the U.S. on November 20, 2015 largely relating to the same matters that were the subject of the ISA Investigation. The Company finalized a settlement agreement with respect to both class actions lawsuits, which was approved by the court on March 22, 2019. Under the terms of the settlement, the classes in all of the actions will receive aggregate consideration of $2.0 million (the "US Settlement"). The US Settlement consideration, as well as ancillary expenses, were funded by the Company's insurance carriers. The US Settlement contains no admission of wrongdoing and reiterates that the Company has always maintained and continues to believe that it did not engage in any wrongdoing or otherwise commit any violation of federal or state securities laws or other laws, including, without limitation, vigorous denials that the Company's public statements were misleading; that the Company failed to disclose any material information from investors; that the Company acted in any deceitful manner; that any investment losses sustained by the classes were caused by the Company or other defendants' alleged misconduct, and that they have any liability to the classes in these actions. The US Settlement also reiterates that the Company's counsel has researched the applicable law and believes that the Company and other defendants can successfully defend against all claims in the actions, and that they continue to believe that the claims asserted in the actions have no merit, and the classes have no evidence to support their claims.

5. On August 13, 2019, the Administrative Enforcement Committee (the "Committee") of the ISA approved an administrative enforcement agreement, titled Enforcement Arrangement ("Enforcement Arrangement"), entered into by and among the ISA, the Company, Isaac Israel, the Company's chief executive officer, Dr. Paul Waymack, the Company's former chairman, and Simcha Rock, the Company's former CFO pursuant to which the Company and each of Messrs. Israel, Waymack and Rock settled the ISA's claims that under Israeli Securities Laws the Company made negligent disclosures in a number of its historical reports filed with the ISA in 2014 and 2015, and the ISA decided to discontinue its criminal investigation and to cease all proceedings against the Company and its principals. As part of the Enforcement Arrangement the Company agreed to pay a fine of NIS 1,500,000 (approximately USD 466,562), payable in 24 consecutive monthly payments, of which USD 322,500 has been paid to date, and the different principals agreed to each pay a fine.

6. On December 21, 2020, the University and BIRAD filed a statement of claim to the court against TyrNovo, the Company, its officers and others. In the claim, the petitioners allege that the University is the rightful owner of a patent owned by TyrNovo. The main remedy sought by the Petitioners is a declaratory relief under which the University is declared the owner of such patent. The Company plan to file a response in April 2021, when it is due. At this preliminary stage the Company is unable, with any degree of certainty, to make any evaluations or any assessments with respect to the probability of success or the scope of potential exposure, if any.

Note 14 - Revenues

Revenues recorded are from payments of license agreements. Such revenues in 2020 and 2019 are from a customer in the U.S and in 2018 from a customer in the far-east.

Notes to the Consolidated Financial Statements

Note 15 - Research and Development Expenses

	For the year ended December 31		
	2020	2019	2018
	USD thousands		
Salaries, wages and related expenses	**1,209**	1,012	933
Share-based payments (see also Note 11)	**756**	238	546
Service providers (*)	**5,523**	1,424	3,789
	7,488	2,674	5,268

(*) The Company has determined that it acts as an agent for certain transactions, see Note 3I. Accordingly, the Company recorded in 2020 USD 961 thousand as an offset of R&D costs and in 2019 USD 532. Receivables and payables regarding such transactions are recorded on a gross basis (see Notes 8 and 9, respectively).

Note 16 - Sales, General and Administrative Expenses

A.

	For the year ended December 31		
	2020	2019	2018
	USD thousands		
Employees and officer's compensation	**1,355**	1,445	1,733
Share-based payments (see also Note 11)	**1,147**	657	87
Legal fees in connection with ISA investigation and class action lawsuits (see also Note 13B)	**43**	356	690
Other professional fees	**1,315**	900	1,525
Board member remuneration and insurance	**962**	622	470
Board member share-based payments	**742**	269	86
FDA Fee	**-**	946	-
ISA settlement (see also Note 13B)	**-**	387	-
Rent and office maintenance	**58**	80	243
Travel and car expenses	**76**	182	228
Depreciation	**235**	178	7
Other	**373**	56	126
	6,306	6,078	5,195

B. The Consolidated Statements of Operations for the year ended December 31, 2020, 2019 and 2018 include refunds from the insurance company in respect of legal expenses in the amount of USD 182, USD 596 and USD 743 thousand, respectiveley.

Note 17 - Other Income

During 2018, the Company acquired Taoz's holdings in TyrNovo. As part of the agreement with Taoz, it waived the rights described in Note 5A(3), and the Company recorded an amount of USD 894 thousand under Other Income, see also Note 5A**.**

Note 18 - Finance Expense (Income), net

A. Expenses (income) on account of warrants

These expenses are related mainly to the fair value adjustments of warrants. The 2020, 2019 and 2018 warrants included a cashless exercise feature, which expired on July 17, 2020, May 20, 2020, September 12, 2019, respectively, when the Company filed a registration statement with the SEC, registering the shares that will derive from future exercise of these warrants. See also Note 21B.

B. Finance expenses

	For the year ended December 31		
	2020	2019	2018
Finance expenses	USD thousands		
Fees and interest expense	**56**	81	9
Loss from exchange rate differences, net	**5**	100	106
Payment to Taoz, see Note 5A(3)	**-**	-	160
Warrant issuance costs	**-**	-	301
	61	181	576

Notes to the Consolidated Financial Statements

Note 19 - Taxes on Income

A. Corporate tax rate

The tax rate applicable to the Group for 2018 - 2020 is 23%.

B. Carry-forward losses

The Company and its subsidiaries incurred losses through 2020, which are not expected to be utilized in the foreseeable future. Therefore, the Group did not record current taxes or deferred taxes.

In 2020, the main reconciling item from the statutory tax rate of the Company (23%, representing theoretical tax benefit of approximately USD 6.4 million) to the effective tax rate (0%) is mainly due to the fact that deferred taxes were not created in respect of carry forward tax losses and in respect of unrecognized expenses for tax purposes such as changes in fair value of warrants.

The carry-forward loss for tax purposes for the Company and its subsidiaries, and the unrecognized research and development expenses, amounts to USD 41 million as of December 31, 2020 (2019 – USD 21 million, 2018 – USD 33.1 million).

C. Tax assessments

The Company's tax assessments are deemed finalized through the end of 2017, pursuant to section 145 of the Israeli Income Tax Ordinance. Tyrnovo's tax assessment is deemed finalized through the end of 2014 and Famewave's tax assessment is open (incorporated on July 2, 2017), pursuant to section 145 of the Israeli Income Tax Ordinance.

During 2019, the Company's tax assessments for Purple Biotech Ltd. for the tax years of 2014 - 2017 were finalized. Following the tax assessments, the Company was required to pay an amount of approximately 250 USD thousands which were recorded as an expense in 2019.

Note 20 - Employee benefits

A. Employee benefits include post-employment benefits and short term benefits.

Balances include:

	For the Year ended December 31	
	2020	**2019**
	USD thousands	**USD thousands**
Short-term benefits	**263**	365
Post-employment benefits	**265**	285

B. Post-employment benefit plans – defined contribution plan

The Company has a defined contribution plan in respect of the Company's liability in respect of its employees who are subject to Section 14 of the Severance Pay Law – 1963.

	For the Year ended December 31		
	2020	**2019**	**2018**
	USD thousands	**USD thousands**	**USD thousands**
Amount recognized as expense in respect of defined contribution plan	**197**	136	95

C. Certain of the Company's senior executives are entitled to annual and special bonuses under the terms of their employment and consulting agreements. These bonuses will become due upon the achievement of certain goals or agreements for the commercialization of the Company's products. These consolidated financial statements include bonuses in the amount of USD 481 thousand for the year ended December 31, 2020, and USD 462 thousand for the year ended December 31, 2019, and USD 777 thousand for the year ended December 31, 2018.

D. Certain of the Company's senior executives are entitled to benefits upon termination of employment under the terms of their employment and consulting agreements, see Note 12 on related parties. These benefits are measured based on the time of service and their monthly pay and the expected term of their employment. These consolidated financial statements include a liability due to these grants of USD 265 thousand USD 285 thousand, as of December 31, 2020 and 2019, respectively.

Notes to the Consolidated Financial Statements

Note 21 - Financial Instruments

Framework for risk management

The Board of Directors has overall responsibility for the establishment and oversight of the Group's risk management framework.

The Group's risk management practice was formulated to identify and analyze the risks that the Group faces, to set appropriate limits for the risks and controls, and to monitor the risks and their compliance with the limits. The risk policy and risk management methods are reviewed regularly to reflect changes in market conditions and in the Group's operations. The Group acts to develop an effective control environment in which all employees understand their roles and commitment.

The Group Audit Committee oversees how management monitors compliance with the Group's risk management policies and procedures, and reviews the adequacy of the risk management framework in relation to the risks faced by the Group. The Group Audit Committee is assisted in its oversight role by Internal Audit. Internal Audit undertakes both regular and ad hoc reviews of risk management controls and procedures, the results of which are reported to the Audit Committee.

A. Risk management

1. Credit risk

Credit risk is the risk of financial loss to the Group if a debtor or counterparty to a financial instrument fails to meet its contractual obligations, and arises mainly from the Company's receivables. The Group restricts exposure to credit risk by investing only in bank deposits.

The Group held cash and cash equivalents and short-term and long-terms deposits of USD 60,876 thousand at December 31, 2020 (2019 – USD 4,395). These are held with banks, which are rated A2, based on Moody's Rating Agency ratings. The short-term deposits, mainly in USD, bear fixed interest ranging between 0.1% - 1.2%, and the long-term deposits, mainly in USD, bear fixed interest of 1.05%.

The carrying amount of cash and cash equivalents and short-term deposits approximate their fair value.

The group has an amount of USD 71 thousand in long term deposits guaranteed for the groups leases and credit.

2. Market risk

Market risk is the risk that changes in market prices, such as foreign currency exchange rates, the CPI, interest rates and the prices of equity instruments, will influence the Group's results or the value of its holdings in financial instruments. The objective of market risk management is to manage and control market risk exposures within acceptable parameters, while optimizing returns.

3. Currency risk

The Group is exposed to currency risk mainly for cash and purchases for research and development expenses that are denominated in dollars and euros. Therefore, the Group is exposed to exchange rate fluctuations in these currencies against the NIS and takes steps to reduce the currency risk by maintaining its liquid resources in accordance with its future needs.

Notes to the Consolidated Financial Statements

Note 21 - Financial Instruments (Cont'd)

Set forth below is a sensitivity test to possible changes in USD/NIS exchange rate as of December 31, 2020:

Sensitive instrument	Income (loss) from change in exchange rate (U.S. dollars in thousands)		Value (U.S. dollars in thousands)	Income (loss) from change in exchange rate (U.S. dollars in thousands)	
	Down 2%	Down 5%		Up 5%	Up 2%
Cash and cash equivalents and deposits	10	24	489	(24)	(10)
Other current assets	30	75	1,500	(75)	(30)
Accounts payable	(10)	(26)	(524)	26	10
Other payables	(40)	(100)	(1,991)	100	40
Post-employment benefit liabilities	(5)	(13)	(265)	13	5
Total income (loss)	(15)	(40)		40	15

B. Financial instruments measured at fair value:

1. In July 2020 and May 2020, the Company registered the warrants issued in May 2020 April 2020, retospectivaly, and therefore they were reclassified from financial liabilities to equity in their fair value using Black & Scholes valuation method.

2. In 2019 a loan of USD 2 million was granted to FameWave was accounted for as a financial asset at fair value (see Note 5B for further information).

3. In September 2019, the Company registered the warrants issued in 2018 and 2019 and therefore they were reclassified from financial liabilities to equity in their fair value using Black & Scholes valuation method.

4. Fair value hierarchy of financial instruments measured at fair value:

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
	USD thousands			
Financial liabilities				
Loan (see Note 5B)	-	-	2,000	2,000

Details regarding fair value measurement at Level 3:

Financial instrument	Valuation method for determining fair value	Significant unobservable inputs	
For the year ended December 31, 2020			
Warrants	Black - Scholes	expected term	**5.3-5.42 years**
		expected volatility	**107.17%-108.9%**
		annual risk free interest	**0.40%-0.50%**
		dividend yield	**0%**
For the year ended December 31, 2019			
Warrants	Black - Scholes	expected term	4.02-4.83 years
		expected volatility	99%
		annual risk free interest	1.95%
		dividend yield	0%

Exhibit 2.1

DESCRIPTION OF SHARE CAPITAL

The following description of our share capital and certain provisions of our articles of association are summaries and do not purport to be complete. The description is qualified by reference to our corporate documents, copies of which are filed with the SEC as exhibits to the Annual Report on Form 20-F of which this Exhibit forms a part.

Authorized Share Capital.

Our authorized share capital is 1,000,000,000 ordinary shares, with no par value, and 50,000,000 non-voting senior preferred shares, with no par value, divided into 5 classes of 10,000,000 preferred shares in each class.

Ordinary Shares

The following is a description of certain rights attached to our ordinary shares.

Voting Rights. Holders of ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders. The ordinary shares do not have preemptive rights, preferred rights or any other right to purchase our securities.

Foreign Ownership. Neither our amended and restated articles of association nor the laws of the State of Israel restrict the ownership or voting of ordinary shares by non-residents of Israel, except under certain circumstances for ownership by nationals of certain countries that are, or have been, in a state of war with Israel.

Transfer of Shares. Our fully paid ordinary shares may generally be freely transferred under our amended and restated articles of association, unless the transfer is restricted or prohibited by applicable law or the rules of the stock exchange on which the shares are traded.

Election of Directors. Under our amended and restated articles of association, the number of directors on our Board of Directors will be no less than four and no more than nine (including any external directors, to the extent that we may be required to appoint external directors in accordance with the Companies Law and any Regulations enacted thereunder) ("Maximum Number"). The majority of the members of the Board shall be residents of Israel, unless our center of management shall have been transferred to another country in accordance with a resolution of our Board by a majority of three quarters (75%) of the participating director votes. The number of directors may be changed, at any time and from time to time, by our shareholders with a majority of (a) 75% of the voting rights participating and voting on the matter in the applicable general meeting of our shareholders and (b) more than 47.9% of all of the voting rights in the Company as of the record date established for the applicable general meeting of our shareholders ("Special Majority"). In accordance with our amended and restated articles of association, the directors elected to serve are divided into three classes, with each class comprising one-third of the members of our Board of Directors (who are not external directors, if any were appointed), (hereinafter the "first class"; the "second class"; and the "third class"). If the number of directors is not equally divisible by three, each of the first class and the second class will be comprised of a different number, the closest and lowest to one-third, while the third class will be comprised of the remaining directors (who are not external directors, if any were appointed). If the number of directors changes, the number of directors in each class will change in accordance with the aforesaid rule. In the annual general meeting of our shareholders that will take place each year, the shareholders shall be entitled to elect directors who shall be elected for a three-year term to replace the class of directors whose term in office has expired as of such annual general meeting of our shareholders. Our Board of Directors may appoint a director at any time to fill any vacancies until the annual meeting of our shareholders set to take place at the end of the three-year term for the class of directors to which such director is so appointed by the Board, provided that the total number of the members of the Board serving at such time will not exceed the Maximum Number. The shareholders may at all times, by a Special Majority vote of the shareholders, dismiss a director. A director to be replaced shall be given a reasonable opportunity to address the shareholders at their meeting. The tenure of a director expires pursuant to the provisions of our amended and restated articles of association and the Companies Law, upon death or if s/he becomes incompetent, unless removed from office as described above.

Dividend and Liquidation Rights. Subject to preferences that may be applicable to any then outstanding preferred shares, our profits, in respect of which a resolution was passed to distribute them as dividend or bonus shares, shall be paid pro rata to the amount of shares held by the shareholders. In the event of our liquidation, the liquidator may, with the general meeting's approval, and subject to any preferences that may be applicable to any then outstanding preferred shares, distribute parts of our property in specie among the shareholders and he or she may, with similar approval, deposit any part of our property with trustees in favor of the shareholders as the liquidator, with the approval mentioned above, deems fit.

Preferred Shares

Pursuant to our amended and restated articles of association, our Board of Directors is authorized to fix, by resolution of the Board of Directors, (i) the number of issued preferred shares (subject to the maximum number of preferred shares authorized in such class), (ii) the designation of such class of preferred shares, and (iii) the preferences, qualifications, and special or relative rights or privileges, which may include, among others, dividend rights, liquidation preferences, conversion rights and redemption rights.

The following is a description of certain rights attached to our preferred shares.

Voting Rights. All preferred shares shall be non-voting shares and shall not vest the holder thereof with any right to participate in the Company's general meetings, to receive notice thereof and/or to vote thereat, except as otherwise specifically required by Israeli law.

So long as any preferred shares are outstanding, the adoption of a resolution, by a regular majority in voting power of the preferred shares who are present, entitled to vote thereon (if any) and voting thereon, voting together as a single class, given in person or by proxy or by an authorized proxy holder, at a meeting of holders of preferred shares shall be necessary for effecting or validating: (i) any amendment or alteration of the memorandum of association or articles of association so as to authorize or create, or increase the authorized amount of, any class or series of shares that will rank senior to the outstanding class or classes of preferred shares as to dividend rights and distribution rights upon the liquidation, winding up or dissolution of our company; (ii) any amendment of any provision of our articles of association so as to adversely affect the special rights, preferences, privileges or voting powers of the preferred shares; and (iii) any consummation of a binding share exchange or reclassification involving the preferred shares, or of a merger or consolidation of our company with or into another entity, unless in each case (x) the Preferred Shares remain outstanding or, in the case of any such merger or consolidation with respect to which the Company is not the surviving or resulting entity (or the Preferred Shares are otherwise exchanged or reclassified), are converted or reclassified into or exchanged for preferred shares of the surviving or resulting entity or its ultimate parent, and (y) such Preferred Shares that remain outstanding or such preferred shares, as the case may be, have rights, preferences, privileges and voting powers of the surviving or resulting entity or its ultimate parent that, taken as a whole, are not materially less favorable to the holders thereof than the rights, preferences, privileges and voting powers, taken as a whole, of the Preferred Shares immediately prior to the consummation of such transaction

The rules and procedures for calling and conducting any meeting of the holders of preferred shares (including, without limitation, the fixing of a record date in connection therewith), the solicitation and use of proxies at such a meeting, the obtaining of written consents and any other procedural aspect or matter with regard to such a meeting or such consents shall be governed by any rules the Board of Directors, in its discretion, may adopt from time to time, which rules and procedures shall conform to the requirements of our amended and restated articles of association, applicable law and, if applicable, the rules of any national securities exchange or other trading facility on which the preferred shares are listed or traded at the time.

Foreign Ownership. Neither our amended and restated articles of association nor the laws of the State of Israel restrict the ownership or voting of preferred shares by non-residents of Israel, except under certain circumstances for ownership by nationals of certain countries that are, or have been, in a state of war with Israel.

Our fully paid preferred shares may generally be freely transferred under our amended and restated articles of association, unless the transfer is restricted or prohibited by applicable law or the rules of the stock exchange on which the shares are traded.

Conversion. Subject to the actual terms of issuance determined by our Board of Directors for any preferred shares when issued, our Preferred Shares may be convertible into our ordinary shares or another series of preferred shares.

Dividend and Liquidation Rights. Issuance of preferred shares by our Board of Directors may result in such shares having dividend or liquidation preferences senior to the rights of the holders of our ordinary shares. Each preferred share shall be entitled to receive upon distribution, and in preference to our ordinary shares, (i) dividends in excess of the general dividends issued to all shareholders including holders of ordinary shares, and/or (ii) amounts paid in a distribution of our surplus assets on winding up, in an amount equal to the original issue price for such preferred shares (adjusted for share combinations or subdivisions or other recapitalizations of our shares), and less the amount of any dividend previously paid in preference, all pro rata to the number of the preferred shares issued and outstanding at such time. Furthermore, and after payment of the preferred shares' dividend preferences or liquidation preferences, each preferred share shall be entitled to receive upon distribution (i) a general dividend issued to all shareholders, (ii) bonus shares, and (iii) amounts paid in a distribution of our surplus assets on winding up, all pro rata to the total number of ordinary shares and preferred shares issued and outstanding at such time.

Although our Board of Directors has no intention at the present time of doing so, it could authorize the issuance of a series of preferred shares that could, depending on the terms of such series, impede the completion of a merger, tender offer, change of control or other takeover attempt.

Exchange Controls

There are currently no material Israeli currency control restrictions on payments of dividends or other distributions with respect to our securities or the proceeds from the sale of our securities, except under certain circumstances, for shareholders who are subjects of countries that are, or have been, in a state of war with Israel or otherwise as set forth in this section. However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time. Israeli residents have an obligation to file reports with the Bank of Israel regarding certain transactions. In addition, Bank of Israel regulations require us to submit regular quarterly update reports concerning foreign investments in the Company.

Access to Corporate Records

Under the Companies Law, shareholders are provided access to minutes of our general meetings, our shareholders register and principal shareholders register, our amended and restated articles of association, our financial statements and any document that we are required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Modification of Class Rights

Under the Companies Law and our amended and restated articles of association, the rights attached to any class of share, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our amended and restated articles of association. According to our amended and restated articles of association, the enlargement of an existing class of shares or the issuance of additional shares thereof, shall not be deemed to modify the rights attached to the previously issued shares of such class or of any other class, unless otherwise provided by the terms of the shares.

Acquisitions under Israeli Law

Special Tender Offer

According to the Companies Law, an acquisition pursuant to which a purchaser will hold a "controlling stake", that is defined as 25% or more of the voting rights if no other shareholder holds a controlling stake, or an acquisition pursuant to which such purchaser will hold more than 45% of the voting rights of the company if no other shareholder owns more than 45% of the voting rights, may not be performed by way of market accumulation, but rather by way of a special tender offer (as defined in the Companies Law) made to all of the company's shareholders on a pro rata basis, or pursuant to a private placement approved by the company's shareholders with the purpose of approving the acquisition of controlling stake, or 45% or more of the company's voting rights. In accordance with the Companies Law, such procedures are not required if the controlling stake or 45% of the company's voting rights are purchased from an existing holder or a controlling stake or 45% of the company's voting rights. A special tender offer may not be consummated unless a majority of the shareholders who announced their stand on such offer have accepted it (in counting the total votes of such shareholders, shares held by the controlling shareholders, shareholders who have personal interest in the offer, shareholders who own 25% or more of the voting rights in the company, relatives or representatives of any of the above or the bidder and corporations under their control, shall not be taken into account). A shareholder may be free to object to such an offer without such objection being deemed as a waiver of his right to sell its respective shares if the transaction is approved by a majority of the company's shareholders despite his objection. In such case, a shareholder who objected to the offer may agree to sell its shares within four days from the last date provided to agree to such an offer. Shares purchased not in accordance with those provisions will become "dormant shares" and will not grant the purchaser any rights so long as they are held by the purchaser.

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer, or shall abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention. In addition, the board of directors must disclose any personal interest each member of the board of directors has in the offer or stems therefrom.

In the event that a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity shall refrain from making a subsequent tender offer for the purchase of shares of the target company and cannot execute a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Full Tender Offer

A person wishing to acquire shares or a class of shares of an Israeli public company and who would, as a result, own more than 90% of the target company's issued and outstanding share capital or of certain class of its shares, is required by the Companies Law to make a full tender offer (as defined in the Companies Law) to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company or class of shares. If either (i) the shareholders who do not accept the offer hold, in the aggregate, less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, or (ii) the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class, then all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a shareholder that had its shares so transferred, whether or not it accepted the tender offer (unless otherwise provided in the offering memorandum), may, within six (6) months from the date of acceptance of the tender offer, petition the court to determine that the tender offer was for less than fair value and that the fair value should be paid as determined by the court. If the shareholders who did not accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class of shares, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Mergers

The Companies Law provides that corporate mergers require the approval of both companies' boards of directors and shareholders. The board of directors of a merging company is required pursuant to the Companies Law to discuss and determine whether in its opinion there exists a reasonable concern that as a result of a proposed merger, the surviving company will not be able to satisfy its obligations towards its creditors, taking into account the financial status of the merging companies. If the board of directors has determined that such a concern exists, it may not approve a proposed merger. In the event, however, that shares of the target company are held by the acquiring company or by a person holding 25% or more of any type of controlling means of the acquiring company, the merger will not be approved if a majority of the shareholders of the target company attending and voting at the meeting at which the merger is considered (without taking into account, for that purpose, the shares held by the acquiring company or by a person holding 25% or more of any type of controlling means of the acquiring company) object to and do not vote in favor of the merger. If a person holds 25% or more of any type of controlling means of more than one merging company, the same provisions shall apply with regard to the shareholders' vote with respect to each such company. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if the court concludes that there exists a reasonable concern that as a result of the merger the surviving company will be unable to satisfy the target company's obligations. Furthermore, a merger may not close unless at least 30 days have passed from the time that the general meeting of each of the merging companies was held and at least 50 days have passed from the date on which the merger proposal was sent to the Israeli Registrar of Companies.

Significant Private Placements

Under the Companies Law, if (i) as a result of a private placement a person would become a controlling shareholder or (ii) a private placement will entitle investors to receive 20% or more of the voting rights of a company as calculated before the private placement, and all or part of the private placement consideration is not in cash or in public traded securities or is not in market terms and if as a result of the private placement the holdings of a substantial shareholder shall increase or as a result of it a person shall become a substantial shareholder, then in either case, the allotment must be approved by the board of directors and by the shareholders of the company. A "substantial shareholder" in connection with a private placement as set forth above, is defined as a shareholder who holds five percent or more of the company's outstanding share capital or voting rights, and which assumes the exercise of all of the securities convertible into shares either held by that person prior to such private placement or offered to such person under the private placement. In order for the private placement to be on "market terms" the board of directors has to determine and explain in detail that the private placement is on market terms, unless proven otherwise. Otherwise, under the Companies Law, a private placement of securities does not require approval at a general meeting of the shareholders of a company; provided however, that in other special circumstances, such as a private placement completed in lieu of a special tender offer, or a private placement under circumstances which qualifies as a related party transaction requiring shareholder approval, approval at a general meeting of the shareholders of a company is then also required. A Registered Direct Offering in the United States is generally considered a private placement under the Companies Law.

Transfer Agent and Registrar

Other than with respect to certain restricted ordinary shares, the shares for a publicly traded company that is listed on TASE (and has ADSs listed on NASDAQ), such as ours, are generally recorded in the name of our Israeli share registrar, Registration Company of United Mizrachi Bank Ltd. Our transfer agent and registrar for our ADSs is the depositary for our ADSs, Bank of New York Mellon, and its address is 101 Barclay Street, New York, NY.

Listing

Our ordinary shares are currently traded on the TASE under the symbol "PPBT." Our ADSs are listed on NASDAQ under the symbol "PPBT".

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

The Bank of New York Mellon, as depositary, registers and delivers our American Depositary Shares, also referred to as ADSs. Each ADS represents ten ordinary shares (or a right to receive ten ordinary shares) deposited with Bank Hapoalim or Bank Leumi, as custodian for the depositary in Israel. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The depositary's office at which the ADSs will be administered is located at 101 Barclay Street, New York, New York 10286. The Bank of New York Mellon's principal executive office is located at One Wall Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Israeli law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR. Directions on how to obtain copies of those documents are provided under the heading "Where You Can Find Additional Information".

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

Cash. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See "Item 10. "Additional Information – D. Taxation – Israeli Tax Considerations and Government Programs - Taxation of Shareholders" for more details. It will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.

Shares. The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. In that case, you will receive no value for them. The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that doing so does not require registration of any securities under the Securities Act of 1933, as amended, or the "Securities Act." If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory assurances from us that such distribution does not require registration of such securities under the Securities Act. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.*

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs for the purpose of withdrawal at the depositary's office. Upon payment of its fees and expenses and of any taxes or governmental charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do you vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of Israel and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed by the holder of the ADSs or as described in the following sentence. If we asked the depositary to solicit your instructions at least 30 days before the meeting date but the depositary does not receive voting instructions from you by the specified date, it will consider you to have authorized and directed it to give a discretionary proxy to a person designated by us to vote the number of deposited securities represented by your ADSs. The depositary will give a discretionary proxy in those circumstances to vote on all questions at to be voted upon unless we notify the depositary that:

- we do not wish to receive a discretionary proxy;
- there is substantial shareholder opposition to the particular question; or
- the particular question would have an adverse impact on our shareholders.

We are required to notify the depositary if one of the conditions specified above exists.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

Fees and Expenses

***Persons depositing or withdrawing shares or ADS holders must pay*:**	***For*:**
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	● Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property ● Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	● Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	● Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	● Depositary services
Registration or transfer fees	● Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	● Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) ● converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	● As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	● As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert foreign currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as an agent, fiduciary or broker on behalf of any other person and earns revenue, including, without limitation, fees and spreads that it will retain for its own account. The spread is the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives in an offsetting foreign currency trade. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or as to the method by which that rate will be determined, subject to its obligations under the deposit agreement.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if:

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist our shares from an exchange on which they were listed and do not list the shares on another exchange;
- we appear to be insolvent or enter insolvency proceedings;
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if we are or it is prevented or delayed by law or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and

- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Right to Receive the Shares Underlying your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;

- when you owe money to pay fees, taxes and similar charges; or

- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Pre-release of ADSs

The deposit agreement permits the depositary to deliver ADSs before deposit of the underlying shares. This is called a pre-release of the ADSs. The depositary may also deliver shares upon cancellation of pre-released ADSs (even if the ADSs are canceled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depositary. The depositary may receive ADSs instead of shares to close out a pre-release. The depositary may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made represents to the depositary in writing that it or its customer owns the shares or ADSs to be deposited; (2) the pre-release is fully collateralized with cash or other collateral that the depositary considers appropriate; and (3) the depositary must be able to close out the pre-release on not more than five business days' notice. In addition, the number of ADSs that may be outstanding at any time as a result of pre-release will not normally exceed 30% of the total number of ordinary shares deposited under the deposit agreement, although the depositary may disregard the limit from time to time if it thinks it is appropriate to do so. The depositary has full discretion as to how and to what extent it may disregard the limit for the amount of ADSs that may be outstanding at any time as a result of the pre-release.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder Communications; Inspection of Register of Holders of ADSs

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

Transfer Agent and Registrar

Our transfer agent and registrar will be the depositary for our ADSs, Bank of New York Mellon, and its address is 101 Barclay Street, New York, NY.

Listing

Our ADSs are listed on The Nasdaq Capital Market under the symbol "PPBT."

KITOV PHARMACEUTICALS HOLDINGS LTD.

2016 EQUITY-BASED INCENTIVE PLAN

1. PURPOSE; TYPES OF AWARDS; CONSTRUCTION.

1.1 Purpose. The purpose of this 2016 Equity-Based Incentive Plan (as may be amended, the "Plan") is to afford an incentive to eligible employees, directors, officers, consultants, advisors, and any other person or entity whose services are considered valuable to Kitov Pharmaceuticals Holdings Ltd., an Israeli company (the "Company"), or any Affiliate of the Company, which now exists or hereafter is organized or acquired by the Company, to increase their efforts on behalf of the Company or an Affiliate and to promote the success of the Company's business, by providing such Grantees with opportunities to acquire a proprietary interest in the Company by the grant of Awards pursuant to the Plan.

1.2. Types of Grants. The Plan is intended to enable the Company to issue Awards under varying tax regimes, including:

(i) pursuant and subject to the provisions of Section 102 of the Ordinance, and all regulations and interpretations adopted thereunder, including the Income Tax Rules (Tax Benefits in Stock Issuance to Employees) 5763-2003 (the "Rules") or such other rules published by the Israeli Income Tax Authorities (the "ITA") (such Awards, "102 Awards"). 102 Awards may either be granted to a Trustee or without a trustee;

(ii) pursuant to Section 3(9) of the Ordinance (such Awards, "3(9) Awards");

(iii) Incentive Stock Options within the meaning of Section 422 of the Code, or the corresponding provision of any subsequently enacted United States federal tax statute, as amended from time to time, to be granted to Grantees who are deemed to be residents of the U.S. for purposes of taxation;

(iv) Nonqualified Stock Options to be granted to Grantees who are deemed to be residents of the U.S. for purposes of taxation; and

(v) other stock-based Awards pursuant to Section 13 hereof.

In addition to the issuance of Awards under the relevant tax regimes in the United States of America and the State of Israel, the Plan contemplates issuances to Grantees in other jurisdictions with respect to which the Committee is empowered to make the requisite adjustments in the Plan and set forth the relevant conditions in the Company's agreement with the Grantee in order to comply with the requirements of the tax regimes in any such jurisdictions.

The Plan contemplates the issuance of Awards by the Company, both as a private company and as a publicly traded company.

1.3. Construction. To the extent any provision herein conflict with the conditions of any relevant tax law or regulation which are relied upon for tax relief in respect of a particular Award to a Grantee, the provisions of such law or regulation shall prevail over those of the Plan, and the Committee is empowered hereunder to interpret and enforce the said prevailing provisions.

2. DEFINITIONS.

2.1. Terms Generally. The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation." Unless the context requires otherwise (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, restated, supplemented or otherwise modified (subject to any restrictions on such amendments, restatements, supplements or modifications set forth therein or herein), (ii) references to any law, constitution, statute, treaty, regulation, rule or ordinance, including any section or other part thereof shall refer to it as amended from time to time and shall include any successor thereof, (iii) reference to a person shall means an individual, partnership, corporation, limited liability company, association, trust, unincorporated organization, or a government or agency or political subdivision thereof, (iv) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Plan in its entirety and not to any particular provision hereof and (v) all references herein to Sections shall be construed to refer to Sections of this Plan.

2.2. Defined Terms. The following terms shall have the meanings ascribed to them in this Section 2:

2.2.1. "Affiliate" shall have the meaning assigned thereto in Rule 405 of Regulation C under the Securities Act. For the purpose of Options granted pursuant to 102 Awards, "Affiliate" shall also mean an "employing company" within the meaning of Section 102(a) of the Ordinance.

2.2.2. "ADS" means an American Depositary Share of the Company.

2.2.2.A "Applicable Law" shall mean any applicable law, rule, regulation, statute, pronouncement, policy, interpretation, judgment, order or decree of any federal, provincial, state or local governmental, regulatory or adjudicative authority or agency, of any jurisdiction, and the rules and regulations of any stock exchange or trading system on which the Shares are then traded or listed.

2.2.3. "Award" shall mean any Option, Restricted Shares, RSU or any other Share-based award, granted to a Grantee under the Plan and any Share issued pursuant to the exercise thereof.

2.2.4. "Board" shall mean the Board of Directors of the Company.

2.2.5. "Code" shall mean the United States Internal Revenue Code of 1986, as amended.

2.2.6. "Committee" shall mean a committee established by the Board to administer the Plan, subject to Section 3.1; the Compensation Committee or the Audit Committee of the Company may fulfill this role.

2.2.7. "Companies Law" shall mean the Israel Companies Law-1999 and the regulations promulgated thereunder, all as amended from time to time.

2.2.8. "Controlling Shareholder" shall have the meaning set forth in Section 32(9) of the Ordinance.

2.2.9. "Disability" shall mean (i) the inability of a Grantee to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months, as determined by a medical doctor satisfactory to the Committee or (ii) if applicable, a "permanent and total disability" as defined in Section 22(e)(3) of the Code, or Section 409A(a)(2)(c)(i) of the Code, as amended from time to time.

2.2.10. "Employee" shall mean a person who is employed by the Company or any of its Affiliates, including, for the purpose of Section 102, an individual who is serving as an "office holder" as defined under the Companies Law, but excluding any Controlling Shareholder.

2.2.11. "Exercise Period" shall mean the period, commencing on the date of grant of an Option, during which an Option shall be exercisable, subject to any vesting provisions thereof and the termination provisions hereof.

2.2.12. "Exercise Price" shall mean the exercise price for each Share covered by an Option, which in any event shall not be less than such minimum exercise price as determined under Applicable Law and/or by a competent authority and/or by the Tel Aviv Stock Exchange and/or by the NASDAQ.

2.2.13. "Fair Market Value" per Share as of a particular date shall mean: (i) the closing sales price per Share on the securities exchange (including, if applicable, the Tel Aviv Stock Exchange or the NASDAQ) on which the Shares are principally traded as quoted on such exchange or system for the last market trading day prior to the time of determination, as reported in The Wall Street Journal or such other source as the Committee deems reliable; without derogating from the above and solely for the purpose of determining the tax liability pursuant to Section 102 of the Ordinance (and in particular Section 102(b)(3)), if on the date of grant the Company's shares are listed on any established stock exchange or a national market system or if the Company's shares will be registered for trading within ninety (90) days following the date of grant under the 102 Capital Gains Track, the Fair Market Value of a Share on its date of grant shall be determined in accordance with the average value of the Company's shares during the thirty (30) trading days immediately preceding the date of grant (if the Company's shares are listed on the date of grant) or during the thirty (30) trading days immediately following the date of registration for trading (if the Company's shares will be listed within ninety (90) days following the date of grant), as the case may be (ii) if the Shares are then quoted in an over-the-counter market, the average of the closing bid and asked prices for the Shares in that over-the-counter market on the last market trading day prior to the day of determination; (iii) if the Shares are not then listed on a securities exchange or quoted in an over-the-counter market, such value as the Committee, in its sole discretion, shall determine, with full authority to determine the method for making such determination, and which determination shall be conclusive and binding on all parties, and shall be made after such consultations with outside legal, accounting and other experts as the Committee may deem advisable; provided, however, that with respect to Nonqualified Stock Options, the Fair Market Value of the Shares shall be determined in a manner that satisfies the applicable requirements of Section 409A of the Code, and with respect to Incentive Stock Options, the Fair Market Value shall be determined in a manner that satisfies the applicable requirements of Section 422 of the Code, subject to Code Section 422(c)(7). The Committee shall maintain a written record of its method of determining such value. If the Shares are listed or quoted on more than one established stock exchange or over-the-counter market, the Committee shall determine the principal such exchange or market and utilize the price of the Shares on that exchange or market (determined as per the method described in clauses (i) or (ii) above, as applicable) for the purpose of determining Fair Market Value.

2.2.14. “Grantee” shall mean an employee, director, officer, consultant, advisor, and any other person or entity who provides with services to the Company or to any Affiliate who was granted an Award under the Plan.

2.2.15. “Non-Employee” shall mean a Grantee who is not an Employee.

2.2.16. “Nonqualified Stock Option” shall mean any Option granted to a Grantee who is deemed to be a resident of the U.S. for purposes of taxation, which Option is not designated as, or does not meet the conditions for, an Incentive Stock Option.

2.2.17. “Options” shall mean all options to purchase Shares granted as 102 Awards, 3(9) Awards, Incentive Stock Options and Non-Qualified Stock Options, as well as options to purchase Shares issued under other tax regimes.

2.2.18. “Ordinance” shall mean the Israeli Income Tax Ordinance (New Version) 1961, and the regulations promulgated thereunder, all as amended from time to time.

2.2.19. “Parent” shall mean any company (other than the Company), which now exists or is hereafter organized, (i) in an unbroken chain of companies ending with the Company if, at the time of granting an Award, each of the companies (other than the Company) owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other companies in such chain, or (ii) if applicable, as defined in Section 424(e) of the Code.

2.2.20. “Retirement” shall mean a Grantee’s retirement pursuant to applicable law or in accordance with the terms of any tax-qualified retirement plan maintained by the Company or any of its affiliates in which the Grantee participates.

2.2.21. “Securities Act” shall mean the U.S. Securities Act of 1933, as amended.

2.2.22. “Shares” shall mean Ordinary Shares, no par value of the Company, and/or an ADS, as the context may require, such other securities as may be substituted for such Share as set forth in this Plan, or shares of such other class of shares of the Company as shall be designated by the Board in respect of the relevant Award.

2.2.23. “Subsidiary” shall mean any company (other than the Company), which now exists or is hereafter organized or acquired by the Company, (i) in an unbroken chain of companies beginning with the Company if, at the time of granting an Award, each of the companies other than the last company in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other companies in such chain, or (ii) if applicable, as defined in Section 424(f) of the Code.

2.2.24. “Ten Percent Shareholder” shall mean a Grantee who, at the time an Incentive Stock Option is granted, owns shares possessing more than ten percent (10%) of the total combined voting power of all classes of shares of the Company or any Parent or Subsidiary.

2.2.25. “Trustee” shall mean the trustee appointed by the Committee or the Board, as the case may be, to hold the respective Options and/or Shares (and, in relation with 102 Awards, approved by the Israeli tax authorities), if so appointed.

3. ADMINISTRATION.

3.1. To the extent permitted under Applicable Law and the Memorandum of Association, Amended and Restated Articles of Association and any other governing document of the Company, the Plan shall be administered by the Committee. In the event that the Board does not create a committee to administer the Plan, the Plan shall be administered by the Board in its entirety. In the event that an action necessary for the administration of the Plan is required under law to be taken by the Board, then such action shall be so taken by the Board. In any such event, all references herein to the Committee shall be construed as references to the Board.

3.2. The Committee shall consist of two or more directors of the Company, as determined by the Board. The Board shall appoint the members of the Committee, it may from time to time remove members from, or add members to, the Committee, and it shall fill vacancies on the Committee however caused, provided that the composition of the Committee shall at all times be in compliance with any mandatory requirements of Applicable Law. The Committee may select one of its members as its Chairman and shall hold its meetings at such times and places as it shall determine. The Committee may appoint a Secretary, who shall keep records of its meetings and shall make such rules and regulations for the conduct of its business, as it shall deem advisable and subject to requirements of Applicable Law.

3.3. Subject to the terms and conditions of this Plan and any mandatory provisions of Applicable Law, and in addition to the Committee's powers contained elsewhere in this Plan, the Committee shall have full authority in its discretion, from time to time and at any time, to determine any of the following, or to recommend to the Board any of the following if it is not authorized to take such action according to Applicable Law:

(i) the identity of eligible Grantees;

(ii) grants of Awards and setting the terms and provisions of Option Agreements (which need not be identical) and any other agreements or instruments under which Awards are made, including, but not limited to, the number of Shares underlying each Award;

(iii) the time or times at which Awards shall be granted;

(iv) the vesting schedule, the vesting milestones (if applicable), the acceleration thereof and conditions on which Awards may be exercised;

(v) the Exercise Price;

(vi) the interpretation of the Plan;

(vii) prescription, amendment and rescission of rules and regulations relating to and for carrying out the Plan, as it may deem appropriate;

(viii) the Fair Market Value of the Shares;

(ix) the tax track (capital gains, ordinary income track or any other track available under the Section 102 of the Ordinance) for the purpose of 102 Awards; and

(x) any other matter which is necessary or desirable for, or incidental to, the administration of the Plan and any Award thereunder.

3.4. Grants of Awards shall be made pursuant to written notice to Grantees setting forth the terms of the Award. Such notice shall designate the type of Award as one or more of the following, subject to Applicable Law: (i) a 102 Award granted to a Trustee (either as a 102 Award (capital gain track) with Trustee or a 102 Award (ordinary income track) with Trustee), (ii) a 102 Award without a Trustee, (iii) a 3(9) Award, (iv) an Incentive Stock Option, (v) a Nonqualified Stock Option, or (vi) any other type of Award.

3.5. Subject to the mandatory provisions of Applicable Law, the grant of any Award, whether by the Committee or the Board, shall be deemed to include an authorization of the issuance of Shares upon the due exercise thereof.

3.6. The authority granted hereunder includes the authority to modify Awards to eligible individuals who are foreign nationals or are individuals who are employed outside Israel to recognize differences in local law, tax policy or custom, in order to effectuate the purposes of the Plan but without amending the Plan. The Committee shall have the authority to grant, in its discretion, to the holder of an outstanding Award, in exchange for the surrender and cancellation of such Award, a new Award having an Exercise Price lower than that provided in the Award so surrendered and canceled and containing such other terms and conditions as the Committee may prescribe in accordance with the provisions of the Plan or to set a new Exercise Price for the same Award lower than that previously provided in the Award, provided that in any event the exercise price shall not be less than such minimum exercise price as determined under Applicable Law and/or by a competent authority and/or by the Tel Aviv Stock Exchange.

3.7. All decisions, determination and interpretations of the Committee shall be final and binding on all Grantees of any Awards under this Plan, unless otherwise determined by the Board. No member of the Committee shall be liable for any action taken or determination made in good faith with respect to the Plan or any Award granted hereunder.

4. ELIGIBILITY.

4.1. Awards may be granted to Grantees of the Company or any Affiliate thereof, taking into account the qualification under each tax regime pursuant to which such Awards are granted. A person who has been granted an Award hereunder may be granted additional Awards, if the Committee shall so determine, subject to the limitations herein. In determining the persons to whom Awards shall be granted and the number of Shares to be covered by each Award, the Committee shall take into account the duties of the respective persons, their present and potential contributions to the success of the Company and such other factors as the Committee shall deem relevant in connection with accomplishing the purpose of the Plan.

4.2. Subject to Applicable Law, 102 Awards may not be granted to Controlling Shareholders and may only be granted to Employees, including officers and directors, of the Company or any Affiliate thereof, who are Israeli residents ("Eligible 102 Grantees"). Awards to Eligible 102 Grantees in Israel shall be 102 Awards. Eligible 102 Grantees may receive only 102 Awards, which may either be grants to a Trustee or grants under Section 102 without a trustee; provided; however, that a 102 Award granted to an Eligible 102 Grantee who is also a citizen or resident for U.S. tax purposes may also be deemed an Incentive Stock Option. Unless otherwise permitted by the Ordinance and the Rules, no 102 Awards to a Trustee may be granted until the expiration of thirty (30) days after the requisite filings under the Ordinance and the Rules have been appropriately made with the ITA.

4.3. Subject to Applicable Law, Non-Employees who are Israeli residents and are not Eligible 102 Grantees may only be granted 3(9) Awards under this Plan.

5. SHARES.

The number of Shares reserved for the grant of Awards under the Plan shall be 15,000,000 Ordinary Shares, no par value of the Company or the equivalent number of ADSs representing such number of Ordinary Shares. All of the Shares reserved for issuance under the Plan may be issued pursuant to the exercise of Incentive Stock Options. The class of Shares shall be designated by the Board with respect to each Award and the notice of grant shall reflect such designation. Any Share underlying an Award granted hereunder which has expired, or was cancelled or terminated or forfeited for any reason without having been exercised, shall be automatically, and without any further action on the part of the Company or any Grantee, returned to the "pool" of reserved Shares hereunder and shall again be available for grant for the purposes of this Plan (unless this Plan shall have been terminated) or unless the Board determines otherwise. Notwithstanding the other provisions of this Section 5, the Board may, subject to any other approvals required under any Applicable Law, increase or decrease the number of Shares to be reserved under the Plan. Such Shares may, in whole or in part, be authorized but unissued Shares or Shares that shall have been or may be reacquired by the Company (to the extent permitted pursuant to the Companies Law) or by a trustee appointed by the Board under the relevant provisions of the Ordinance, the Companies Law or any equivalent provision. Any Shares that are not subject to outstanding Awards at the termination of the Plan shall cease to be reserved for the purpose of the Plan, but until termination of the Plan, the Company shall at all times reserve a sufficient number of Shares to meet the requirements of the Plan.

6. TERMS AND CONDITIONS OF OPTIONS.

Each Option granted pursuant to the Plan shall be evidenced by a written agreement between the Company and the Grantee or a written notice delivered by the Company and accepted by the Grantee (an "Option Agreement"), in such form and containing such terms and conditions as the Committee shall from time to time approve, which Option Agreement shall comply with and be subject to the following terms and conditions, unless otherwise specifically provided in such Option Agreement or the terms referred to in Sections 9 and 10 below. For purposes of interpreting this Section 6, a director's service as a member of the Board or the services of an officer, as the case may be, shall be deemed to be employment with the Company or its Subsidiary or Affiliate.

6.1. Number of Shares. Each Option Agreement shall state the number of Shares covered by the Option.

6.2. Type of Option. Each Option Agreement shall specifically state the type of Option granted thereunder and whether it constitutes an Incentive Stock Option, Nonqualified Stock Option, 102 Option Award and the relevant track, 3(9) Option Award, and/or otherwise.

6.3. Exercise Price. Each Option Agreement shall state the Exercise Price. In the case of an Incentive Stock Option, the Exercise Price shall not be less than one hundred percent (100%) of the Fair Market Value of the Shares covered by the Option on the date of grant or such other price as may be required pursuant to the Code. For an Incentive Stock Option granted to any Ten-Percent Shareholder, the Exercise Price shall be no less than 110% of the Fair Market Value of the Shares covered by the Option on the date of grant. The Exercise Price of a Nonqualified Stock Option shall not be less than 100% of the Fair Market Value of the Shares on the date of grant unless the Committee specifically indicates that the Option will have a lower Exercise Price and the Option complies with Section 409A of the Code. In the case of any other Option, the per share Exercise Price shall be equal to the Fair Market Value of the Shares on the date of grant, or such other price as shall be determined by the Committee, provided, however, that in no event shall the Exercise Price of an Option be less than the par value of the shares for which such Option is exercisable. Subject to Section 3 and to the foregoing, the Committee may reduce the Exercise Price of any outstanding Option. The Exercise Price shall also be subject to adjustment as provided in Section 14 hereof. This Section 6.3 shall not apply to an Option granted pursuant to assumption of, or substitution for, another option in a manner that complies with Code Section 424(a), whether or not the Option is an Incentive Stock Option. In any event the exercise price shall not be less than such minimum exercise price as determined under Applicable Law and/or by a competent authority and/or by the Tel Aviv Stock Exchange.

6.4. Manner of Exercise. An Option may be exercised, as to any or all Shares as to which the Option has become exercisable, by written notice delivered in person or by mail to the Secretary of the Company or to such other person as determined by the Committee, specifying the number of Shares with respect to which the Option is being exercised, accompanied by payment of the Exercise Price for such Shares in the manner specified in the following sentence. Payment for Shares acquired pursuant to Options granted hereunder shall be made in full, upon exercise of the Options: (i) in immediately available funds, or by certified or bank cashier's check payable to the Company, (ii) solely to the extent permitted by Applicable Law and authorized by the Committee, by delivery of Shares to the Company (either by actual delivery or attestation) having a value equal to the Exercise Price, (iii) solely to the extent permitted by Applicable Law and authorized by the Committee, by a broker-assisted cashless exercise in accordance with procedures approved by the Committee under Regulation T as promulgated by the Federal Reserve Board, whereby payment of the Option exercise price or tax withholding obligations may be satisfied, in whole or in part, with Shares subject to the Option by delivery of an irrevocable direction to a securities broker (on a form prescribed by the Committee) to sell Shares and to deliver all or part of the sale proceeds to the Company in payment of the aggregate exercise price and, if applicable, the amount necessary to satisfy the Company's withholding obligations prior to the issuance of the Shares subject to the Option, (iv) solely to the extent permitted by Applicable Law and authorized by the Committee, by delivery of a notice of "net exercise" to the Company, pursuant to which the Company will reduce the number of Shares issuable upon exercise by the largest whole number of Shares with a Fair Market Value that does not exceed the aggregate Exercise Price); provided, however, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate Exercise Price not satisfied by such reduction in the number of whole shares to be issued or (v) by any other means approved by the Committee and specified in the Award Agreement, which may include procedures for cashless exercise. Anything herein to the contrary notwithstanding, if the Committee determines that any form of payment available hereunder would be in violation of Section 402 of the Sarbanes-Oxley Act of 2002, such form of payment shall not be available.

6.5. Term and Vesting of Options. Each Option Agreement shall provide the vesting schedule for the Option as determined by the Committee. To the extent permitted under Applicable Law, the Committee shall have the authority to determine the vesting schedule and accelerate the vesting of any outstanding Option at such time and under such circumstances as it, in its sole discretion, deems appropriate, including, for avoidance of doubt, acceleration for change of control as such is defined in an agreement with the applicable Grantee. The Option Agreement may contain performance goals and measurements, and the provisions with respect to any Option need not be the same as the provisions with respect to any other Option. The Exercise Period of an Option will be 10 years from the date of grant of the Option unless otherwise determined by the Committee, but subject to the vesting provisions described above and the early termination provisions set forth in Sections 6.6 and 6.7 hereof; provided, however, that in the case of an Incentive Stock Option granted to a Ten Percent Shareholder, such Exercise Period shall not exceed five (5) years from the date of grant of such Option. At the expiration of the Exercise Period, all unexercised Options shall become null and void.

6.6. Termination.

6.6.1. Except as provided in this Section 6.6 and in Section 6.7 hereof, an Option may not be exercised unless the Grantee is then in the employ of or maintaining a director, officer, consultant, advisor or supplier relationship with the Company or a Subsidiary or Affiliate thereof or, in the case of an Incentive Stock Option, a company or a parent or subsidiary company of such company issuing or assuming the Option in a transaction to which Section 424(a) of the Code applies, and unless the Grantee has remained continuously so employed or in the director, officer, supplier, consultant, or advisor relationship since the date of grant of the Option. In the event that the employment or director, officer or consultant, advisor or supplier relationship of a Grantee shall terminate (other than by reason of death, Disability or Retirement), all Options of such Grantee that are vested and exercisable at the time of such termination may, unless earlier terminated in accordance with their terms, be exercised within up to twelve (12) months after the date of such termination (or such different period as the Committee shall prescribe); provided, however, that if the Company (or the Subsidiary or Affiliate, when applicable) shall terminate the Grantee's employment or service for Cause (as defined below) or if, whether or not the Grantee's employment is terminated by either party, circumstances arise or are discovered with respect to the Grantee that would have constituted Cause for termination of his or her employment or service, all Options theretofore granted to such Grantee (whether vested or not) shall, to the extent not theretofore exercised, terminate on the date of such termination (or on which such circumstances arise or are discovered, as the case may be) unless otherwise determined by the Committee.

6.6.2. In the case of a Grantee whose principal employer is a Subsidiary or Affiliate, the Grantee's employment shall also be deemed terminated for purposes of this Section 6.6 as of the date on which such principal employer ceases to be such Subsidiary or Affiliate. Notwithstanding anything to the contrary, the Committee, in its absolute discretion may, on such terms and conditions as it may determine appropriate, extend the periods for which the Options held by any individual may continue to vest and be exercisable; provided, that such Options may lose their status as Incentive Stock Options under applicable law and be deemed Nonqualified Stock Options as a result of the modification of the Option to extend the exercise period and/or in the event that the Option is exercised beyond the later of: (i) three (3) months after the date of termination of the employment relationship ; or (ii) the applicable period under Section 6.7 below with respect to a termination of the employment relationship because of the death, Disability or Retirement of Grantee.

6.6.3. For purposes of this Plan, the term "Cause" shall mean any of the following: (a) fraud, embezzlement or felony or similar act by the Grantee; (b) an act of moral turpitude by the Grantee, or any act that causes significant injury to the reputation, business, assets, operations or business relationship of the Company (or a Subsidiary or Affiliate, when applicable); (c) any material breach by the Grantee of an agreement between the Company or any Subsidiary or Affiliate and the Grantee (including material breach of confidentiality, non-competition or non-solicitation covenants) or of any duty of the Grantee to the Company or any Subsidiary or Affiliate thereof; or (d) any circumstances that constitute grounds for termination for cause under the Grantee's employment, consulting or service agreement with the Company or Subsidiary or Affiliate, to the extent applicable.

6.7. Death, Disability or Retirement of Grantee. If a Grantee shall die while employed by, or performing service for, the Company or a Subsidiary, or within the three (3) month period after the date of termination of such Grantee's employment or service (or within such different period as the Committee may have provided pursuant to Section 6.6 hereof), or if the Grantee's employment or service shall terminate by reason of Disability, all Options theretofore granted to such Grantee may (to the extent otherwise vested and exercisable and unless earlier terminated in accordance with their terms), be exercised by the Grantee or by the Grantee's estate or by a person who acquired the right to exercise such Options by bequest or inheritance or otherwise by result of death or Disability of the Grantee, at any time within one (1) year after the death or Disability of the Grantee (or such different period as the Committee shall prescribe). In the event that an Option granted hereunder shall be exercised by the legal representatives of a deceased or former Grantee, written notice of such exercise shall be accompanied by a certified copy of letters testamentary or equivalent proof of the right of such legal representative to exercise such Option. In the event that the employment or service of a Grantee shall terminate on account of such Grantee's Retirement, all Options of such Grantee that are exercisable at the time of such Retirement may, unless earlier terminated in accordance with their terms, be exercised at any time within the three (3) month period after the date of such Retirement (or such different period as the Committee shall prescribe).

6.8. Suspension of Vesting. Unless the Board of Directors or the Committee provides otherwise, vesting of Options granted hereunder shall be suspended during any unpaid leave of absence, other than in the case of any (a) periods of legally protected leave of absence pursuant to Applicable Law, (b) leave of absence which was pre-approved by the Company for purposes of continuing the vesting of Options, or (c) transfers between locations of the Company or between the Company, any Affiliate, or any respective successor thereof.

6.9. Other Provisions. The Option Agreement evidencing Awards under the Plan shall contain such other terms and conditions not inconsistent with the Plan as the Committee may determine, at or after the date of grant, including without limitation, provisions in connection with the restrictions on transferring the Awards, which shall be binding upon the Grantees and other terms and conditions as the Committee shall deem appropriate.

6.10. Israeli Index Base for 102 Awards. Each 102 Award will be subject to the Israeli index base of the Value of Benefit, as defined in Section 102 (a) of the Ordinance, as determined by the Committee in its discretion, pursuant to the Rules, from time to time. In the event that the Company effects a public offering of its shares in any stock exchange outside of Israel, the Committee may amend retroactively the Israeli index base, pursuant to the Rules, without the Grantee's consent.

6.11. Securities Law Restrictions. Except as otherwise provided in the applicable Option Agreement or other agreement between the Grantee and the Company, if the exercise of an Option following the termination of the Grantee's employment or service (other than for Cause) would be prohibited at any time solely because the issuance of Shares would violate the registration requirements under the Securities Act, then the Option shall terminate on the earlier of (i) the expiration of a period of six (6) months after the termination of the Grantee's employment or service during which the exercise of the Option would not be in violation of such registration requirements, or (ii) the expiration of the term of the Option as set forth in the Option Agreement.

7. NONQUALIFIED STOCK OPTIONS.

Options granted pursuant to this Section 7 are intended to constitute Nonqualified Stock Options and shall be subject to the general terms and conditions specified in Section 6 hereof and other provisions of the Plan, except for any provisions of the Plan applying to Options under different tax laws or regulations. Nonqualified Stock Options may not be granted to Grantees who are providing services only to a "parent" of the Company, as such term is defined in Rule 405 of Regulation C under the Securities Act, unless the Shares underlying such Awards are treated as "service recipient stock" under Section 409A of the Code because the Awards are granted pursuant to a corporate transaction (such as a spin off transaction) or unless such Awards comply with the distribution requirements of Section 409A of the Code.

8. INCENTIVE STOCK OPTIONS.

Options granted pursuant to this Section 8 are intended to constitute Incentive Stock Options and shall be granted subject to the following special terms and conditions, the general terms and conditions specified in Section 6 hereof and other provisions of the Plan, except for any provisions of the Plan applying to Options under different tax laws or regulations:

8.1. Eligibility for Awards. Incentive Stock Options may be granted only to Employees of the Company, or to Employees of a Parent or Subsidiary corporation thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). No more than 15,000,000 Ordinary Shares may be issued as a result of the exercise of Incentive Stock Options granted under the Plan.

8.2. Value of Shares. The aggregate Fair Market Value (determined as of the date the Incentive Stock Option is granted) of the Shares with respect to which all Incentive Stock Options granted under this Plan and all other option plans of any Parent or Subsidiary corporation become exercisable for the first time by each Grantee during any calendar year shall not exceed one hundred thousand United States dollars ($100,000) with respect to such Grantee. To the extent that the aggregate Fair Market Value of Shares with respect to which the Incentive Stock Options are exercisable for the first time by any Grantee during any calendar years exceeds one hundred thousand United States dollars ($100,000), such Options shall be treated as Nonqualified Stock Options. The foregoing shall be applied by taking Options into account in the order in which they were granted, with the Fair Market Value of any Share to be determined at the time of the grant of the Option. In the event that the foregoing results in the portion of an Incentive Stock Option exceeding the one hundred thousand United States dollars ($100,000) limitation, only such excess shall be treated as a Nonqualified Stock Option.

8.3. Ten Percent Shareholder. In the case of an Incentive Stock Option granted to a Ten Percent Shareholder, (i) the Exercise Price shall not be less than one hundred and ten percent (110%) of the Fair Market Value of the Shares on the date of grant of such Incentive Stock Option, and (ii) the Exercise Period shall not exceed five (5) years from the date of grant of such Incentive Stock Option.

8.4. Incentive Stock Option Lock-Up Period. No disposition of Shares received pursuant to the exercise of Incentive Stock Options (" ISO Shares"), shall be made by the Grantee within 2 years from the date of grant, nor within 1 year after the transfer of such ISO Shares to the Grantee. To the extent that the Grantee violates the aforementioned limitations, the Incentive Stock Options shall be deemed to be Nonqualified Stock Options.

8.5. Approval. The status of any ISO Shares shall be subject to approval of the Plan by the Company's shareholders, for the purposes of qualifying the Plan with respect to the issuance of ISO Shares, and such approval to be provided 12 months before or after the date of adoption of the Plan by the Board of Directors.

8.6. Exercise Following Termination. Notwithstanding anything else in this Plan to the contrary, Incentive Stock Options that are not exercised within three (3) months following termination of a Grantee's employment in the Company or its Parent or Subsidiary corporations, or within one year in case of termination of Grantee's employment in the Company or its Parent or Subsidiary corporations due to a Disability (within the meaning of section 22(e)(3) of the Code), shall be deemed to be Nonqualified Stock Options.

8.7. Adjustments to Incentive Stock Options. Any Option Agreement providing for the grant of Incentive Stock Options shall indicate that adjustments made pursuant to the Plan with respect to Incentive Stock Options could constitute a "modification" of such Incentive Stock Options (as that term is defined in Section 424(h) of the Code) or could cause adverse tax consequences for the holder of such Incentive Stock Options and that the holder should consult with his or her tax advisor regarding the consequences of such "modification" on his or her income tax treatment with respect to the Incentive Stock Option.

8.8. Notice to Company of Disqualifying Disposition. Each Grantee who receives an Incentive Stock Option must agree to notify the Company in writing immediately after the Grantee makes a Disqualifying Disposition of any ISO Shares. A "Disqualifying Disposition" is any disposition (including any sale) of such ISO Shares before the later of (i) two years after the date the Grantee was granted the Incentive Stock Option, or (ii) one year after the date the Grantee acquired Shares by exercising the Incentive Stock Option. If the Grantee dies before such ISO Shares are sold, these holding period requirements do not apply and no disposition of the ISO Shares will be deemed a Disqualifying Disposition.

9. 102 AWARDS.

9.1. The Company may elect to grant Awards to Grantees pursuant to this Section 9 through either (a) Section 102(b)(2) of the Ordinance as capital gains track Awards ("102 Capital Gains Track Awards"), or (b) Section 102(b)(1) of the Ordinance as ordinary income track Awards (" 102 Ordinary Income Track Awards", and together with 102 Capital Gains Track Awards, "102 Trustee Awards"). 102 Trustee Awards shall be granted subject to the following special terms and conditions contained in this Section 9, the general terms and conditions specified in Sections 6, 11 and 12 hereof and other provisions of the Plan, except for any provisions of the Plan applying to Awards under different tax laws or regulations.

9.2. The Company may grant only one type of 102 Trustee Awards at any given time to all Grantees who are to be granted 102 Trustee Awards pursuant to this Plan, and shall file an election with the ITA regarding the type of 102 Trustee Award it elects to grant before the date of grant of any 102 Trustee Awards (the "Election"). Such Election shall also apply to any bonus shares received by any Grantee as a result of holding the 102 Trustee Awards. The Company may change the type of 102 Trustee Awards that it elects to grant only after the passage of at least 12 months from the end of the year in which the first grant was made in accordance with the previous Election, or as otherwise provided by Applicable Law. Any Election shall not prevent the Company from granting Awards pursuant to Section 102(c) of the Ordinance without a Trustee (" 102 Non-Trustee Awards").

9.3. Each 102 Trustee Award will be deemed granted on the date stated in a written notice to be provided by the Company, provided that on or before such date (i) the Company has provided such notice to the Trustee and (ii) the Grantee has signed all documents required pursuant to Applicable Law and under the Plan.

9.4. Each 102 Trustee Award, each Share issued pursuant to the exercise of any 102 Trustee Award, and any rights granted thereunder, including, without limitation, bonus shares, shall be allotted and issued to and registered in the name of the Trustee and shall be held in trust for the benefit of the Grantee for a period of not less than the requisite period prescribed by the Ordinance and the Rules or such longer period as set by the Committee (the "Required Holding Period"). In the event that the requirements under Section 102 to qualify an Award as a 102 Trustee Award are not met, then the Award may be treated as a 102 Non-Trustee Award, all in accordance with the provisions of Section 102 and the Rules. After termination of the Required Holding Period, the Trustee may release such 102 Trustee Awards and any such Shares, provided that (i) the Trustee has received an acknowledgment from the ITA that the Grantee has paid any applicable taxes due pursuant to the Ordinance or (ii) the Trustee and/or the Company and/or its Affiliate withholds any applicable taxes due pursuant to the Ordinance arising from the 102 Trustee Awards and/or any Shares allotted or issued upon exercise of such 102 Trustee Awards. The Trustee shall not release any 102 Trustee Awards or Shares issued upon exercise thereof prior to the payment in full of the Grantee's tax liabilities arising from such 102 Trustee Awards and/or Shares or the withholding referred to in (ii) above.

9.5. Each 102 Trustee Award shall be subject to the relevant terms of the Ordinance and the Rules, which shall be deemed an integral part of the 102 Trustee Award and shall prevail over any term contained in the Plan or Award Agreement that is not consistent therewith. Any provision of the Ordinance, the Rules and any approvals by the Income Tax Commissioner not expressly specified in this Plan or an Option Agreement, Restricted Share Agreement, Restricted Share Unit Agreement or any other agreement entered into in connection with an Award that, as determined by the Committee, are necessary to receive or maintain any tax benefit pursuant to Section 102 shall be binding on the Grantee. Each Grantee granted a 102 Trustee Award shall comply with the Ordinance and the terms and conditions of the Trust Agreement entered into between the Company and the Trustee. Each Grantee agrees to execute any and all documents that the Company and/or its Affiliates and/or the Trustee may reasonably determine to be necessary in order to comply with the Ordinance and the Rules.

9.6. During the Required Holding Period, each Grantee shall not release from trust or sell, assign, transfer or give as collateral, the Shares issuable upon the exercise of a 102 Trustee Awards and/or any securities issued or distributed with respect thereto, until the expiration of the Required Holding Period. Notwithstanding the above, if any such sale or release occurs during the Required Holding Period it will result in adverse tax consequences to the Grantee under Section 102 of the Ordinance and the Rules, which shall apply to and shall be borne solely by such Grantee. Subject to the foregoing, the Trustee may, pursuant to a written request from a Grantee, release and transfer such Shares to a designated third party, provided that both of the following conditions have been fulfilled prior to such release or transfer: (i) payment has been made to the ITA of all taxes required to be paid upon the release and transfer of the Shares, and confirmation of such payment has been received by the Trustee; and (ii) the Trustee has received written confirmation from the Company that all requirements for such release and transfer have been fulfilled according to the terms of the Company's corporate documents, the Plan, the relevant Option Agreement and any Applicable Law.

9.7. If a 102 Trustee Award is exercised during the Required Holding Period, the Shares issued upon such exercise shall be issued in the name of the Trustee for the benefit of the Grantee. If such 102 Trustee Award is exercised after the expiration of the Required Holding Period, the Shares issued upon such exercise shall, at the election of the Grantee, either (i) be issued in the name of the Trustee, or (ii) be issued to the Company's Nominee Company for the benefit of Grantee, provided that the Grantee first complies with all applicable provisions of the Plan and all taxes with respect thereto shall have been fully paid to the ITA.

9.8. The foregoing provisions of this Section 9 relating to 102 Trustee Awards shall not apply with respect to 102 Non-Trustee Awards, which shall, however, be subject to the relevant provisions of Section 102 and the Rules.

9.9. Upon receipt of a 102 Trustee Award, a Grantee will sign an undertaking to release the Trustee from any liability with respect to any action or decision duly taken and executed in good faith by the Trustee in relation to the Plan, or any 102 Trustee Award or Share granted to such Grantee thereunder.

10. 3(9) AWARDS.

10.1. Awards granted pursuant to this Section 10 are intended to constitute 3(9) Awards and shall be granted subject to the general terms and conditions specified in Section 6 hereof and other provisions of the Plan, except for any provisions of the Plan applying to Awards under different tax laws or regulations.

10.2. To the extent required by the Ordinance or the ITA or otherwise deemed by the Committee prudent or advisable, 3(9) Awards granted pursuant to the Plan shall be issued to a Trustee nominated by the Committee in accordance with the provisions of the Ordinance. In such event, the Trustee shall hold such Awards in trust, until exercised by the Grantee, pursuant to the Company's instructions from time to time as set forth in a trust agreement, which will be entered into between the Company and the Trustee. If determined by the Board or the Committee, and subject to such trust agreement, the Trustee shall be responsible for withholding any taxes for which a Grantee may become liable upon the exercise of Awards.

11. RESTRICTED SHARES

The Committee may award Restricted Shares to any eligible Grantee, including under Section 102 of the Ordinance. Each Award of Restricted Shares under the Plan shall be evidenced by a written agreement between the Company and the Grantee (a "Restricted Share Agreement"), in such form as the Committee shall from time to time approve. Each Restricted Share Agreement shall comply with and be subject to the following terms and conditions, unless otherwise specifically provided in such Agreement:

11.1. Number of Shares. Each Restricted Share Agreement shall state the number of Shares covered by an Award.

11.2. Purchase Price. Each Restricted Share Agreement may state a purchase price amount to be paid by the Grantee, if any, in consideration for the issuance of Restricted Shares and the terms of payment thereof, which may include payment by issuance of promissory notes or other evidence of indebtedness on such terms and conditions as determined by the Committee.

11.3. Vesting. Each Restricted Share Agreement shall provide the vesting schedule for Restricted Shares as determined by the Committee, provided that (to the extent permitted under Applicable Law) the Committee shall have the authority to determine the vesting schedule and accelerate the vesting of any outstanding Restricted Share at such time and under such circumstances as it, in its sole discretion, deems appropriate, including, for avoidance of doubt, acceleration for change of control as such is defined in an agreement with the applicable Grantee.

11.4. Restrictions. Restricted Shares may not be sold, assigned, transferred, pledged, hypothecated or otherwise disposed of, except by will or the laws of descent and distribution, for such period as the Committee shall determine from the date on which an Award is granted (a "Restricted Period"). The Committee may also impose such additional or alternative restrictions and conditions on Restricted Shares as it deems appropriate, including the satisfaction of performance criteria. Such performance criteria may include, but are not limited to, sales, earnings before interest and taxes, return on investment, earnings per share, any combination of the foregoing or rate of growth of any of the foregoing, as determined by the Committee. Certificates for shares issued pursuant to Restricted Share Awards shall bear an appropriate legend referring to such restrictions, and any attempt to dispose of any such shares in contravention of such restrictions shall be null and void and without effect. Such certificates may, if so determined by the Committee, be held in escrow by an escrow agent appointed by the Committee, or, if a Restricted Share Award is made pursuant to Section 102, by the Trustee. In determining the Restricted Period of an Award, the Committee may provide that the foregoing restrictions shall lapse with respect to specified percentages of the awarded Restricted Shares on successive anniversaries of the date of such Award.

11.5. Adjustment of Performance Goals. The Committee may adjust performance goals to take into account changes in law and accounting and tax rules and to make such adjustments as the Committee deems necessary or appropriate to reflect the inclusion or the exclusion of the impact of extraordinary or unusual items, events or circumstances. The Committee also may adjust the performance goals by reducing the amount to be received by any Grantee pursuant to an Award if and to the extent that the Committee deems it appropriate.

11.6. Forfeiture. Subject to such exceptions as may be determined by the Committee, if a Grantee's continuous employment with the Company or any Subsidiary or Affiliate shall terminate for any reason prior to the expiration of the vesting date or Restricted Period of an Award or prior to the payment in full of the purchase price for any Restricted Shares with respect to which the vesting date or the Restricted Period has expired, any Shares remaining subject to vesting or restrictions or with respect to which the purchase price has not been paid in full, shall thereupon be forfeited and shall be deemed transferred to, and reacquired by, or cancelled by, as the case may be, the Company or a Subsidiary at no cost to the Company or Subsidiary, subject to all Applicable Laws. Upon forfeiture of Restricted Shares, the Grantee shall have no further rights with respect to such Restricted Shares.

11.7. Ownership. During a Restricted Period, a Grantee shall possess all incidents of ownership of Restricted Shares, subject to Sections 6.9 and 11.4, including the right to vote and receive dividends with respect to such Shares. All distributions, if any, received by a Grantee with respect to Restricted Shares as a result of any stock split, stock dividend, combination of shares, or other similar transaction shall be subject to the restrictions applicable to the original Award.

12. RESTRICTED SHARE UNITS.

12.1. A Restricted Share Unit ("RSU") is an Award covering a number of Shares that is settled by issuance of those Shares. An RSU may be awarded to any eligible Grantee, including under Section 102 of the Ordinance. Each grant of RSUs under the Plan shall be evidenced by a written agreement between the Company and the Grantee (the "Restricted Share Unit Agreement"), in such form as the Committee shall from time to time approve. RSUs shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan. The provisions of various Restricted Share Unit Agreements entered into under the Plan need not be identical. RSUs may be granted in consideration of a reduction in the recipient's other compensation.

12.2. Other than the par value of the Shares, no payment of cash shall be required as consideration for RSUs. RSUs may or may not be subject to vesting. Vesting shall occur, in full or in installments, upon satisfaction of the conditions specified in the relevant Restricted Share Unit Agreement.

12.3. Without limitation of Section 6.9, no voting or dividend rights as a shareholder shall exist prior to the actual issuance of Shares in the name of a Grantee. Notwithstanding anything else in this Plan (as may be amended from time to time) to the contrary, unless otherwise specified by the Committee, each RSU shall be for a term of ten (10) years. Each Restricted Share Unit Agreement shall specify its term and any conditions on the time or times for settlement, and provide for expiration prior to the end of its term in the event of termination of employment or service providing to the Company, and may provide for earlier settlement in the event of a Grantee's death, Disability or other events.

12.4. Settlement of vested RSUs shall be made in the form of Shares. Distribution to a Grantee of an amount (or amounts) from settlement of vested RSUs can be deferred to a date after settlement as determined by the Committee. The amount of a deferred distribution may be increased by an interest factor or by dividend equivalents. Until a grant of RSUs is settled, the number of such RSUs shall be subject to adjustment pursuant hereto.

12.5. Notwithstanding anything to the contrary set forth herein, any RSUs granted under the Plan that are not exempt from the requirements of Section 409A of the Code shall contain such restrictions or other provisions so that such RSUs will comply with the requirements of Section 409A of the Code. Such restrictions, if any, shall be determined by the Board and contained in the Restricted Share Unit Agreement evidencing such RSU Award. For example, such restrictions may include, without limitation, a requirement that any Shares that are to be issued in a year following the year in which the RSU Award vests must be issued in accordance with a fixed, pre-determined schedule.

13. OTHER SHARE OR SHARE-BASED AWARDS.

The Committee may grant other Awards under the Plan pursuant to which Shares (which may, but need not, be Restricted Shares pursuant to Section 11 hereof), cash or a combination thereof, are or may in the future be acquired or received, or Awards denominated in stock units, including units valued on the basis of measures other than market value. The Committee may also grant stock appreciation rights without the grant of an accompanying Option, which rights shall permit the Grantees to receive, at the time of any exercise of such rights, cash equal to the amount by which the Fair Market Value of all Shares in respect of which the right was granted exceeds the exercise price thereof. The Committee may grant to Grantees (including Employees), and it is hereby deemed to be an Award under the terms of the Plan, the opportunity to purchase Shares of the Company in connection with any public offerings of the Company's securities, including a rights offering to Shareholders of the Company. Such other Share based Awards may be granted alone, in addition to, or in tandem with, any Award of any type granted under the Plan and must be consistent with the purposes of the Plan.

14. EFFECT OF CERTAIN CHANGES.

14.1. General. In the event of a subdivision of the outstanding share capital of the Company, a recapitalization, a reorganization (which may include a combination or exchange of shares), a consolidation, a stock split, a reverse stock split, a spin-off or other corporate divestiture or division, a reclassification or other similar occurrence, the Committee shall make such adjustments as determined by it to be appropriate in order to adjust (i) the number of Shares available for grants of Awards, (ii) the number of Shares covered by outstanding Awards, and (iii) the exercise price per Share covered by any Award; provided, however, that any fractional Shares resulting from such adjustment shall be rounded down to the nearest whole Share, and the Company shall have no obligation to make any cash or other payment with respect to such fractional Shares, and provided that in any event the exercise price shall not be less than NIS 0.30 (or equivalent in other currency) or such other minimum exercise price as determined under applicable law and/or by a competent authority and/or by the Tel Aviv Stock Exchange.

14.2. Merger and Sale of Company. In the event of (i) a sale of all or substantially all of the assets of the Company; or (ii) a sale (including an exchange) of all or substantially all of the shares of the Company, or an acquisition by a shareholder of the Company or by an Affiliate of such shareholder, of all of the shares of the Company held by other shareholders or by other shareholders who are not Affiliated with such acquiring party; (iii) a merger, consolidation, amalgamation or like transaction of the Company with or into another corporation; (iv) a scheme or arrangement for the purpose of effecting such sale, merger or amalgamation; or (v) such other transaction or set of circumstances that is determined by the Committee, in its discretion, to be a transaction having a similar effect (all such transactions being herein referred to as a "Merger/Sale"), then, without the Grantee's consent and action and without any prior notice requirement:

14.2.1. Unless otherwise determined by the Committee in its sole and absolute discretion, any Award then outstanding shall be assumed or an equivalent Award shall be substituted by such successor corporation of the Merger/Sale or any Parent or Affiliate thereof as determined by the Board in its discretion (the "Successor Corporation"), under substantially the same terms as the Award.

For the purposes of this Section 14.2.1, the Award shall be considered assumed if, following a Merger/Sale, the Award confers on the holder thereof the right to purchase or receive, for each Share underlying an Award immediately prior to the Merger/Sale, either (i) the consideration (whether stock, cash, or other securities or property) distributed to or received by holders of Shares in the Merger/Sale for each Share held on the effective date of the Merger/Sale (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares), which may be subject to vesting and other terms as determined by the Committee in its discretion, or (ii) regardless of the consideration received by the holders of Shares in the Merger/Sale, solely shares (or their equivalent) of the Successor Corporation at a value to be determined by the Committee in its discretion, which may be subject to vesting and other terms as determined by the Committee in its discretion. The foregoing shall not limit the Committee's authority to determine, in its sole discretion, that in lieu of such assumption or substitution of awards of the Successor Corporation for Awards, any other type of asset or property will be substituted for an Award, including under Section 14.2.2 hereunder.

14.2.2. In the event that Awards are not assumed or substituted for by equivalent awards, the Committee may (but shall not be obligated to), in lieu of such assumption of, or substitution for, an Award, and in its sole discretion, (i) provide for a Grantee to have the right to exercise an Award, or otherwise accelerate vesting of an Award, as to all or part of the Shares covered thereby, including Shares covered by the Award which would not otherwise be exercisable or vested, under such terms and conditions as the Committee shall determine, including the cancellation of all unexercised Awards upon closing of the Merger/Sale; and/or (ii) provide for the cancellation of each outstanding Award at the closing of such Merger/Sale, and payment to the Grantee of an amount in cash as determined by the Committee to be fair under the circumstances (with full authority to determine the method for making such determination, which may be the Black-Scholes model or any other method, and which determination shall be conclusive and binding on all parties, and which may be zero if the value of the Shares underlying an Option is determined to be less than the Exercise Price therefor), and subject to such terms and conditions as may be determined by the Committee. Payments under this provision may be delayed to the same extent that payment of consideration to the holders of the Company's Shares in connection with the Merger/Sale is delayed as a result of escrows, earn outs, holdbacks or any other contingencies.

14.2.3. Notwithstanding the foregoing, in the event of a Merger/Sale, the Committee may determine, in its sole discretion, that upon completion of such Merger/Sale, the terms of any Award shall be otherwise amended, modified or terminated, as the Committee shall deem in good faith to be appropriate, and if an Option Award, that the Option Award shall confer the right to purchase or receive any other security or asset, or any combination thereof, or that its terms be otherwise amended, modified or terminated, as the Committee shall deem in good faith to be appropriate. Neither the authorities and powers of the Committee under this Section 14.2, nor the exercise or implementation thereof, shall (i) be restricted or limited in any way by any adverse consequences (tax or otherwise) that may result to any holder of an Award, and (ii) as, inter alia , being a feature of the Award upon its grant, be deemed to constitute a change or an amendment of the rights of such holder under this Plan, nor shall any such adverse consequences (as well as any adverse tax consequences that may result from any tax ruling or other approval or determination of any relevant tax authority) be deemed to constitute a change or an amendment of the rights of such holder under this Plan.

14.2.4. The Committee need not take the same action with respect to all Awards or with respect to all Grantees. The Committee may take different actions with respect to the vested and unvested portions of an Award.

14.3 Effect of distributions and rights offerings.

14.3.1 In case of bonus share distribution in which the record date is prior to the exercise date of vested Options, then the quantity of shares to which the Grantee is entitled upon exercise of such Options will be increased by the number of shares to which the Grantee would have been entitled to receive as bonus shares, had such Grantee exercised such vested options no later than the trading day preceding the Ex-benefit date. The exercise price of the options will remain unchanged. The provisions applicable to Shares issued pursuant to the exercise of Options (including without limitation the provisions relating to the Required Holding Period pursuant to section 9.4 above) shall apply to all Shares issuable upon exercise of such Options.

14.3.2 In the event that the Company shall offer to its shareholders any securities by way of a rights issue, the exercise price of the Options and the quantity of Shares issuable upon exercise of the Options will not be adjusted, however the Company shall offer, or cause to be offered, rights to Grantees mutatis mutandis, in such quantity as the Grantees would have been entitled in the event that they had exercised their vested Options one day prior to the record date for the rights issuance. The provisions herein applicable to Shares issued pursuant to the exercise of Options (including without limitation the provisions relating to the Required Holding Period pursuant to section 9.4 above) shall apply to all securities issuable in such manner to Grantees pursuant to the rights offering (if any) - with the exception of such quantity of the securities with an Ex-rights value equal to the amount invested by the Grantee in exercising the rights, which securities shall be transferred (beneficially) to the Company's Nominee Company for the benefit of Grantee following issuance thereof.

14.3.3. Cash dividend distribution. No adjustments in the purchase price or quantity of options shall be implemented in the event of distribution of a cash dividend by the Company to its shareholders.

14.4. Reservation of Rights. Except as expressly provided in this Section 14, the Grantee of an Award hereunder shall have no rights by reason of any subdivision or consolidation of shares of any class or the payment of any stock dividend (bonus shares), any other increase or decrease in the number of shares of any class or by reason of any dissolution, liquidation, Merger/Sale, or consolidation, divestiture or spin-off of assets or shares of another company. Any issue by the Company of shares of any class, or securities convertible into shares of stock of any class, shall not affect, and no adjustment by reason thereof shall be made with respect to, the number, type or price of shares subject to an Award. The grant of an Award pursuant to the Plan shall not affect in any way the right or power of the Company to make adjustments, reclassifications, reorganizations or changes to its capital or business structures or to merge, consolidate, dissolve, liquidate, sell or transfer all or part of its business or assets or engage in any similar transactions.

14.5. In accordance with directives of the Tel Aviv Stock Exchange, due to transition to clearance on day T+1 for shares and convertible securities, and to the extent the Tel Aviv Stock Exchange bylaws shall not determine otherwise, no Options shall be exercised on the effective date for bonus share distribution, rights offering, dividend distribution, share capital split, reverse-split or reduction (hereinafter: a "Corporate Event"). Furthermore, in the event that the Ex-day for a Corporate Event shall occur prior to the effective date for a Corporate Event, no Options may be exercised on said Ex-day.

15. NON-TRANSFERABILITY OF AWARDS; SURVIVING BENEFICIARY.

15.1. All Awards granted under the Plan shall not be transferable otherwise than by will or by the laws of descent and distribution, unless otherwise determined by the Board or under this Plan, provided that with respect to Shares issued upon exercise of Options, the restrictions on transfer shall be the restrictions referred to in Section 16 (Conditions Upon Issuance of Shares) hereof. Awards may be exercised or otherwise realized, during the lifetime of a Grantee, only by the Grantee or by his or her guardian or legal representative, to the extent provided herein. Any transfer of an Award not permitted hereunder (including transfers pursuant to any decree of divorce, dissolution or separate maintenance, any property settlement, separation agreement or any other agreement with a spouse) and any grant of any interest in any Award to, or creation in any way of any interest in any Award by, any party other than a Grantee shall be null and void and shall not confer upon any party or person, other than the Grantee, any rights. A Grantee may file with the Committee a written designation of a beneficiary on such form as may be prescribed by the Committee and may, from time to time, amend or revoke such designation. If no designated beneficiary survives the Grantee, the executor or administrator of the Grantee's estate shall be deemed to be the Grantee's beneficiary. Notwithstanding the foregoing, upon the request of a Grantee and subject to Applicable Law, the Committee, at its sole discretion, may permit the Grantee to transfer an Award to a family trust.

15.2. As long as Shares are held by a Trustee in favor of a Grantee, all rights possessed by the Grantee over the Shares are personal, and may not be transferred, assigned, pledged or mortgaged, other than by will or laws of descent and distribution.

16. CONDITIONS UPON ISSUANCE OF SHARES

16.1. Legal Compliance. Shares shall not be issued pursuant to the exercise or settlement of an Award, unless the exercise or settlement of such Award and the issuance and delivery of such Shares shall comply with Applicable Laws as determined by counsel to the Company. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary for the lawful issuance and sale of any Shares hereunder, and the inability to issue Shares hereunder due to non-compliance with any Company policies with respect to the sale of Shares, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority or compliance shall not have been obtained or achieved. Shares issued pursuant to an Award shall be subject to the Amended and Restated Articles of Association of the Company and any other governing documents of the Company, including all policies, manuals and internal regulations adopted by the Company from time to time, as may be amended from time to time, including, without limitation, any provisions included therein concerning restrictions or limitations on transferability of Shares or grant of any rights with respect thereto and any provisions concerning restrictions on the use of inside information and other provisions deemed by the Company to be appropriate in order to ensure compliance with Applicable Law, statutes and regulations.

16.2. Investment Representations. As a condition to the exercise of an Award, the Company may require the person exercising such Award to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares, and to make other representations as may be required under applicable securities laws, if, in the opinion of counsel for the Company, such representations are required, all in form and content specified by the Company.

17. MARKET STAND-OFF

17.1. In connection with any underwritten public offering by the Company of its equity securities pursuant to an effective registration statement filed under the Securities Act or equivalent law in another jurisdiction, a Grantee shall not directly or indirectly, without the prior written consent of the Company or its underwriters, (i) lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Shares acquired under this Plan or any securities of the Company (whether or not acquired under this Plan), or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Shares acquired under this Plan, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Shares acquired under this Plan or such other securities, in cash or otherwise. Such restriction (the "Market Stand-Off") shall be in effect for such period of time following the effective date of the registration statement relating to such offering as may be requested by the Company or such underwriters, provided, however, that in any event, such period shall not exceed 90 days following the effective date of such registration statement.

17.2. In the event of a subdivision of the outstanding share capital of the Company, the declaration and payment of a stock dividend (distribution of bonus shares), the declaration and payment of an extraordinary dividend payable in a form other than stock, a recapitalization, reorganization (which may include a combination or exchange of shares or a similar transaction affecting the Company's outstanding securities without receipt of consideration), a consolidation, stock split, spin-off or other corporate divestiture or division, a reclassification or other similar occurrence, an adjustment in conversion ratio, any new, substituted or additional securities which are by reason of such transaction distributed with respect to any Shares subject to the Market Stand-Off, or into which such Shares thereby become convertible, shall immediately be subject to the Market Stand-Off.

17.3. In order to enforce the Market Stand-Off, the Company may impose stop-transfer instructions with respect to the Shares acquired under this Plan until the end of the applicable stand-off period.

17.4. The underwriters in connection with a registration statement so filed are intended to be third party beneficiaries of this Section 17 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto.

18. AGREEMENT BY GRANTEE REGARDING TAXES.

18.1. If the Committee shall so require, as a condition of exercise of an Award, the release of Shares by the Trustee or the expiration of the Restricted Period, a Grantee shall agree that, no later than the date of such occurrence, he or she will pay to the Company or make arrangements satisfactory to the Committee and the Trustee (if applicable) regarding payment of any applicable taxes of any kind required by Applicable Law to be withheld or paid.

18.2. Each Option Agreement, Restricted Share Agreement, and Restricted Share Unit Agreement and each other agreement in connection with an Award under the Plan shall contain the following agreement and acknowledgment of the Grantee:

ALL TAX CONSEQUENCES UNDER ANY APPLICABLE LAW WHICH MAY ARISE FROM THE GRANT OF ANY AWARDS OR THE EXERCISE THEREOF, THE SALE OR DISPOSITION OF ANY SHARES GRANTED HEREUNDER OR ISSUED UPON EXERCISE OF ANY AWARD OR FROM ANY OTHER ACTION OF A GRANTEE IN CONNECTION WITH THE FOREGOING SHALL BE BORNE AND PAID SOLELY BY SUCH GRANTEE, AND THE GRANTEE SHALL INDEMNIFY THE COMPANY, ITS SUBSIDIARIES AND AFFILIATES AND THE TRUSTEE, AND SHALL HOLD THEM HARMLESS AGAINST AND FROM ANY LIABILITY FOR ANY SUCH TAX OR PENALTY, INTEREST OR INDEXATION THEREON. EACH GRANTEE AGREES TO, AND UNDERTAKES TO COMPLY WITH, ANY RULING, SETTLEMENT, CLOSING AGREEMENT OR OTHER SIMILAR AGREEMENT OR ARRANGEMENT WITH ANY TAX AUTHORITY IN CONNECTION WITH THE FOREGOING WHICH IS APPROVED BY THE COMPANY. EACH GRANTEE IS ADVISED TO CONSULT WITH A TAX ADVISOR WITH RESPECT TO THE TAX CONSEQUENCES OF RECEIVING OR EXERCISING AWARDS HEREUNDER. THE COMPANY DOES NOT ASSUME ANY RESPONSIBILITY TO ADVISE A GRANTEE ON SUCH MATTERS, WHICH SHALL REMAIN SOLELY THE RESPONSIBILITY OF SUCH GRANTEE.

18.3. The Company or any Subsidiary or Affiliate may take such action as it may deem necessary or appropriate, in its discretion, for the purpose of or in connection with withholding of any taxes which the Company or any Subsidiary or Affiliate is required by any Applicable Law to withhold in connection with any Awards (collectively, "Withholding Obligations"). Such actions may include, without limitation, (i) requiring a Grantee to remit to the Company in cash an amount sufficient to satisfy such Withholding Obligations; (ii) subject to Applicable Law, allowing a Grantee to surrender Shares to the Company, in an amount that at such time, reflects a value that the Committee determines to be sufficient to satisfy such Withholding Obligations; (iii) withholding Shares otherwise issuable upon the exercise of an Award at a value which is determined by the Committee to be sufficient to satisfy such Withholding Obligations; or (iv) any combination of the foregoing. The Company shall not be obligated to allow the exercise of any Award by or on behalf of a Grantee until all tax consequences arising from the exercise of such Award are resolved in a manner acceptable to the Company.

18.4. Each Grantee shall notify the Company in writing promptly and in any event within ten (10) days after the date on which such Grantee first obtains knowledge of any tax bureau inquiry, audit, assertion, determination, investigation, or question relating in any manner to the Awards granted or received hereunder or Shares issued hereunder and shall continuously inform the Company of any developments, proceedings, discussions and negotiations relating to such matter, and shall allow the Company and its representatives to participate in any proceedings and discussions concerning such matters. Upon request, a Grantee shall provide to the Company any information or document relating to any matter described in the preceding sentence, which the Company, in its discretion, requires.

18.5. With respect to 102 Non-Trustee Awards, if a Grantee ceases to be engaged by the Company or any Affiliate, the Grantee shall extend to the Company and/or its Affiliate with whom the Grantee is employed a security or guarantee for the payment of taxes due at the time of sale of Shares, all in accordance with the provisions of Section 102 of the Ordinance and the Rules.

19. RIGHTS AS A SHAREHOLDER; VOTING AND DIVIDENDS.

19.1. Subject to Section 11.7, a Grantee shall have no rights as a shareholder of the Company with respect to any Shares covered by an Award until the Grantee shall have exercised the Award (in the case of an Option or similar Award), paid the exercise price (to the extent applicable) and become the record holder of the subject Shares. In the case of 102 Option Awards or 3(9) Option Awards (if such Options are being held by a Trustee), the Trustee shall have no rights as a shareholder of the Company with respect to the Shares covered by such Award until the Trustee becomes the record holder of such Shares for the Grantee's benefit, and the Grantee shall have no rights as a shareholder of the Company with respect to the Shares covered by the Award until the date of the release of such Shares from the Trustee to the Company's Nominee Company for the benefit of Grantee and the transfer of record (beneficial) ownership of such Shares to the Grantee. No adjustment shall be made for dividends (ordinary or extraordinary, whether in cash, securities or other property) or distribution of other rights for which the record date is prior to the date on which the Grantee or Trustee (as applicable) becomes the beneficial record holder of the Shares covered by an Award, except as provided in Section 14 hereof.

19.2. With respect to all Awards issued in the form of Shares hereunder or upon the exercise of Awards hereunder, any and all voting rights attached to such Shares shall be subject to Section 6.9, and the Grantee shall be entitled to receive dividends distributed with respect to such Shares, subject to the provisions of the Company's Articles of Association, as amended from time to time, and subject to any Applicable Law.

19.3. The Company may, but shall not be obligated to, register or qualify the sale of Shares under any applicable securities law or any other applicable law.

19.4 It is clarified that all Shares and other tradable securities of the Company are held by either the Company's Nominee Company acting as custodian for such securities (at the Effective Date - the Registration Company of Bank Mizrachi), or the depositary for the Company's ADS program (at the Effective Date - The Bank of New York Mellon) and accordingly all Shares and other tradable securities which may be issued to Grantee as a result of the exercise of Options shall be issued under the name of the Nominee Company with instructions that Grantee shall be listed as beneficial shareholder of record.

20. NO REPRESENTATION BY COMPANY.

By granting Awards, the Company is not, and shall not be deemed as, making any representation or warranties to a Grantee regarding the Company, its business affairs, its prospects or the future value of its Shares.

21. NO RETENTION RIGHTS.

Nothing in the Plan or in any Award granted or agreement entered into pursuant hereto shall confer upon any Grantee the right to continue in the employ of, or be in a consultant, advisor, director, officer or supplier relationship with, the Company or any Subsidiary or Affiliate or to be entitled to any remuneration or benefits not set forth in the Plan or such agreement or to interfere with or limit in any way the right of the Company or any such Subsidiary or Affiliate to terminate such Grantee's employment or service. Awards granted under the Plan shall not be affected by any change in duties or position of a Grantee as long as such Grantee continues to be employed by, or be in a consultant, advisor, director, officer or supplier relationship with, the Company or any Subsidiary or Affiliate.

22. PERIOD DURING WHICH AWARDS MAY BE GRANTED.

Awards may be granted pursuant to the Plan from time to time within a period of ten (10) years from the Effective Date. From and after the tenth (10^{th}) anniversary of the Effective Date no grants of Awards may be made and the Plan shall continue to be in full force and effect solely with respect to such Awards that remain outstanding. The Plan shall terminate at such time after the tenth (10^{th}) anniversary of the Effective Date as no Awards remain outstanding.

23. TERM OF AWARD

Anything herein to the contrary notwithstanding, but without derogating from the provisions of Sections 6.6, 6.7 or 8.3 hereof, if any Award, or any part thereof, has not been exercised and the Shares covered thereby not paid for within the term of the Award as determined by the Committee, which in any event shall not exceed ten (10) years after the date on which the Award was granted, as set forth in the Notice of Grant in the Grantee's Award, such Award, or such part thereof, and the right to acquire such Shares, shall terminate, and all interests and rights of the Grantee in and to the same shall expire. In the case of Shares held by a Trustee, the Grantee shall elect whether to release such Shares from trust or sell the Shares and upon such release or sale such trust shall expire.

24. AMENDMENT AND TERMINATION OF THE PLAN.

The Board at any time and from time to time may suspend, terminate, modify or amend the Plan, whether retroactively or prospectively; provided, however, that, unless otherwise determined by the Board, an amendment which requires shareholder approval in order for the Plan to continue to comply with any Applicable Law shall not be effective unless approved by the requisite vote of shareholders, and provided further, that except as provided herein, no suspension, termination, modification or amendment of the Plan may adversely affect any Award previously granted, without the written consent of Grantees holding a majority in interest of the Awards so affected, and in the event that such consent is obtained, all Awards so affected shall be deemed amended, and the holders thereof shall be bound, as set forth in such consent.

25. APPROVAL.

25.1. The Plan shall take effect upon its adoption by the Board (the "Effective Date"), except that solely with respect to grants of Incentive Stock Options the Plan shall also be subject to approval within one year of the Effective Date, by a majority of the votes cast on the proposal at a meeting or a written consent of shareholders. Failure to obtain approval by the shareholders shall not in any way derogate from the valid and binding effect of any grant of an Award that is not an Incentive Stock Option. Upon approval of the Plan by the shareholders of the Company as set forth above, all Incentive Stock Options granted under the Plan on or after the Effective Date shall be fully effective as if the shareholders of the Company had approved the Plan on the Effective Date. Notwithstanding the foregoing, in the event that approval of the Plan by the shareholders of the Company is required under Applicable Law, in connection with the application of certain tax treatment or pursuant to applicable stock exchange rules or regulations or otherwise, such approval shall be obtained within the time required under the Applicable Law.

25.2. The 102 Awards are subject to the approval, if required, of the ITA and receipt by the Company of all approvals thereof.

26. RULES PARTICULAR TO SPECIFIC COUNTRIES; SECTION 409A

Notwithstanding anything herein to the contrary, the terms and conditions of the Plan may be amended with respect to a particular country by means of an appendix to the Plan, and to the extent that the terms and conditions set forth in any appendix conflict with any provisions of the Plan, the provisions of the appendix shall govern. Terms and conditions set forth in the Appendix shall apply only to Awards granted to Grantees under the jurisdiction of the specific country that is the subject of the appendix and shall not apply to Awards issued to Grantees not under the jurisdiction of such country. The adoption of any such appendix shall be subject to the approval of the Board or Committee, and if required in connection with the application of certain tax treatment, pursuant to applicable stock exchange rules or regulations, or otherwise, also the approval of the requisite majority of the shareholders of the Company. To the extent applicable, the Plan and any agreement hereunder shall be interpreted in accordance with Section 409A of the Code. Notwithstanding any provision of the Plan to the contrary, in the event that, following the Effective Date, the Board determines that any Award may be subject to Section 409A of the Code, the Board may adopt such amendments to the Plan and to the relevant agreement governing the Award or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Board determines are necessary or appropriate to (a) exempt the Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Award or (b) comply with the requirements of Section 409A of the Code.

27. GOVERNING LAW; JURISDICTION.

The Plan and all determinations made and actions taken pursuant hereto shall be governed by the laws of the State of Israel, except with respect to matters that are subject to tax laws, regulations and rules in any specific jurisdiction, which shall be governed by the respective laws, regulations and rules of such jurisdiction. Certain definitions, which refer to laws other than the laws of such jurisdiction, shall be construed in accordance with such other laws. The courts of competent jurisdiction located in Tel-Aviv-Jaffa, Israel shall have exclusive jurisdiction over any dispute arising out of or in connection with this Plan and any Award granted hereunder, and by signing any agreement relating to an Award hereunder each Grantee irrevocably submits to such exclusive jurisdiction.

28. NON-EXCLUSIVITY OF THE PLAN.

Neither the adoption of the Plan by the Board nor the submission of the Plan to shareholders of the Company for approval (to the extent required under Applicable Law), shall be construed as creating any limitations on the power or authority of the Board to adopt such other or additional incentive or other compensation arrangements of whatever nature as the Board may deem necessary or desirable or preclude or limit the continuation of any other plan, practice or arrangement for the payment of compensation or fringe benefits to employees generally, or to any class or group of employees, which the Company or any Subsidiary now has lawfully put into effect, including, without limitation, any retirement, pension, savings and stock purchase plan, insurance, death and disability benefits and executive short-term or long-term incentive plans.

29. MISCELLANEOUS.

29.1. Additional Terms. Each Award awarded under the Plan may contain such other terms and conditions not inconsistent with the Plan as may be determined by the Committee, in its sole discretion.

29.2. Severability. If any provision of the Plan or any Option Agreement, Restricted Share Agreement, Restricted Share Unit Agreement or any other agreement entered into in connection with an Award shall be determined to be illegal or unenforceable by any court of law in any jurisdiction, the remaining provisions hereof and thereof shall be severable and enforceable in accordance with their terms, and all provisions shall remain enforceable in any other jurisdiction. In addition, if any particular provision contained in the Plan or any Option Agreement, Restricted Share Agreement, Restricted Share Unit Agreement or any other agreement entered into in connection with an Award shall for any reason be held to be excessively broad as to duration, geographic scope, activity or subject, it shall be construed by limiting and reducing such provision as to such characteristic so that the provision is enforceable to fullest extent compatible with the Applicable Law as it shall then appear.

29.3. Captions and Titles. The use of captions and titles in this Plan or any Option Agreement, Restricted Share Agreement Restricted Share Unit Agreement or any other agreement entered into in connection with an Award is for the convenience of reference only and shall not affect the meaning of any provision of the Plan or such agreement.

THE SYMBOL "[****]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

FIRST AMENDMENT TO PRODUCT MANUFCTURING AGREEMENT

This **FIRST AMENDMENT TO PRODUCT MANUFACTURING AGREEMENT** ("*Amendment*") is made as of the date of signature of the last Party to execute this Amendment ("Amendment Effective Date"), by and between:

KITOV PHARMA LTD., an Israeli company with offices at 132 Menachem Begin Road, Azrieli Center, Tel Aviv 6701101, Israel ("**Kitov**"); and

DEXCEL PHARMA TECHNOLOGIES LTD., an Israeli company having its principal place of business at 10 Hakidma St., Yokneam, 2069200, Israel ("**Dexcel**").

WHEREAS: On November 11, 2018, Kitov and Dexcel entered into a Product Manufacturing Agreement ("**Original Agreement**"), pursuant to which Dexcel will manufacture a combination tablet of Celecoxib and Amlodipine Besylate ("**Product**") for Kitov for Kitov's distribution world-wide through various Distributors (as such term is defined in the Original Agreement); and

WHEREAS: Kitov has signed an agreement with a Distributor, Coeptis Pharmaceuticals, Inc. ("**Coeptis**") (and Coeptis has signed an agreement with and delegated certain distribution responsibilities under its agreement with Kitov to a third party sub-distributor), for the distribution of the Product in the United States, and Kitov has signed and anticipates signing other agreements with Distributors for the distribution of the Product in other territories; and

WHEREAS: The Original Agreement provides that Dexcel will supply the Product solely to Kitov based on purchase orders from Kitov submitted to and confirmed by Dexcel in accordance with the terms of the Original Agreement, and that Dexcel has no contractual responsibility to any of Kitov's Distributors; and

WHEREAS: Kitov and Dexcel together own the Joint IP (the definition of which is incorporated as Exhibit A of the Original Agreement) for the Product, and Kitov and Dexcel desire to further protect their respective rights to such Joint IP by clarifying Kitov's ability to disclose Joint IP information to third parties (including, without limitation, potential and actual Distributors and their agents); and

WHEREAS: Kitov and Dexcel desire to amend the Original Agreement for the following purposes:

(a) to modify certain of the supply conditions relating to the Product,
(b) to clearly state that Kitov is and shall remain fully responsible to Dexcel under the Original Agreement for any acts and/or failures to act by any Distributor in any country,
(c) to clarify insurance requirements of a Distributor to assure Dexcel that any Distributor will be adequately insured against claims relating to the Product in the Distributor's country,
(d) to clarify when and how a Party may disclose any Confidential Information (including, *inter alia*, any Confidential Information which is, includes, or refers to the Joint IP) to an unaffiliated third party for any purpose, and
(e) to add an additional package size and price to the list of Products.

Unless otherwise defined in this Amendment, all initially capitalized terms in this Amendment have the meaning assigned in the Original Agreement.

NOW, THEREFORE, the Parties agree from and after the Amendment Effective Date as follows:

1. Section 1.12 of the Original Agreement is hereby deleted and the following new Section 1.12 is substituted in lieu thereof:

   "1.12 "**Distributors**" shall mean any Person under contract with Kitov and/or any of its Affiliates and/or its Distributors for the distribution of the Product in a certain territory or territories."

2. Sections 1.27 and 1.28 of the Original Agreement are hereby deleted and the following new Sections 1.27 and 1.28 are substituted in lieu thereof:

   "1.27 "**Minimum Order Requirements**" shall mean multiples of a full Batch. Each Batch may be divided among different Liveries; provided that, for each Livery, such order shall be comprised of a minimum of [****] Packs.

   "1.28 "**Pack**" shall mean a bottle containing 30, 100 or 500 tablets of the Product, Labeled with an agreed Livery."

3. New Section 2.3 is hereby added following Section 2.2 of the Original Agreement:

   "2.3 Distributors

      "2.3.1 Kitov shall not disclose to any Person any part of the Joint IP without Dexcel's prior written consent (which shall not be unreasonably withheld). Kitov undertakes to use its best efforts to protect the Parties' Intellectual Property Rights with respect to the Joint IP, including, *inter alia*, by submitting any documentation, application, filing, registration or the like required to perfect or enforce the Parties' interests in any Joint IP under the statutory Intellectual Property Right protection mechanisms of any country in which the Product is being distributed (including, without limitation, any correspondence or other communication with any patent or copyright office or other governmental authority with respect thereto) (each, a "**Filing**"). Dexcel shall reasonably cooperate with Kitov with respect to the foregoing at Kitov's expense. Each Filing shall be considered as "Confidential Information" of the Parties and subject to the provisions of Article 7 hereof.

      "2.3.2 The provisions of this Agreement, as amended from time to time, shall be considered as "Confidential Information" of the Parties and subject to the provisions of Article 7 hereof. The Parties may agree on a redacted version of the Agreement which Kitov may share with prospective or current Distributors."

"2.3.3 Kitov shall be solely responsible for any and all acts and omissions of any Distributor hereunder, and shall undertake to ensure that any such Distributor shall fully comply with the provisions of this Agreement. Kitov warrants that each contract it or its Affiliate enters into with a Distributor will include a requirement that the Distributor maintain both comprehensive general liability insurance and product liability insurance in the amounts and with coverage limits substantially similar to those as set forth for the Parties in Section 8.6 of the Agreement. Kitov undertakes, in each such contract:

(a) to include provisions substantially similar to those set forth in Article 7 (Confidentiality) and Sections 8.1.5 and 8.1.6, and

(b) to use its reasonable efforts to have a clause including Dexcel as a third party beneficiary of such agreement for the purposes of enforcing Dexcel's rights against any Distributor in its capacity as a sub-licensee of the Joint IP and/or a Distributor of the Product.

4. Section 3.1.1 of the Original Agreement is hereby deleted and the following new Section 3.1.1 is substituted in lieu thereof:

"3.1.1 Kitov shall provide (or shall ensure that the Distributor shall provide) Dexcel with the Product Packaging and Labelling instructions, including, but not limited to, approved artwork, with respect to any new SKU (for a new Product Distributor or a new country), as well as changes to or destruction of existing materials, at least one hundred and twenty (120) days prior to the anticipated first supply of each such SKU; provided that the parties acknowledge that Dexcel is not required to commence production for such new SKU before the relevant artwork is approved by Dexcel and Kitov (or its Distributor) for printing."

5. Section 3.3.6 of the of the Original Agreement is hereby deleted and the following new Section 3.3.6 is substituted in lieu thereof:

"3.3.6 Dexcel shall supply the Product with eighty percent (80%) of the shelf life remaining upon Delivery, unless otherwise agreed by the Parties; provided that, at such time as the approved shelf life for the Product is 48 months, Dexcel shall supply the Product with eighty-five percent (85%) of the shelf life remaining upon Delivery.

6. Section 3.6 of the Original Agreement is hereby deleted and the following new Section 3.6 is substituted in lieu thereof:

"3.2 The Supply Prices for commercial Batches of the Product by Dexcel to Kitov shall be:

Strength	**Pack Size**	**Supply Price/Pack (in US Dollars)**
200/2.5mg	Bottle 30 tablets	[****]
200/2.5mg	Bottle 100 tablets	[****]
200/2.5mg	Bottle 500 tablets	[****]
200/5mg	Bottle 30 tablets	[****]
200/5mg	Bottle 100 tablets	[****]
200/5mg	Bottle 500 tablets	[****]
200/10mg	Bottle 30 tablets	[****]
200/10mg	Bottle 100 tablets	[****]
200/10mg	Bottle 500 tablets	[****]

7. New Section 3.10, immediately following Section 3.9, is hereby added to the Original Agreement:

"3.10 Additional Costs

"3.10.1 PQR Costs. Dexcel shall prepare a periodic Product Quality Review for the Product ("PQR") in accordance with the provisions of the Quality Agreement. Kitov may, upon request and during normal business hours, review the PQR at Dexcel's facilities, without cost. In the event that Kitov or a Distributor requests a copy of the PQR, Dexcel shall provide a copy of the requested documentation, subject to the payment by Kitov or such Distributor of Dexcel's standard cost for a copy of the PQR ([****] for each Product SKU)."

"3.10.2 Datalogger Costs. In order to record temperature conditions during transport, temperature data loggers shall be used with all shipments to record temperature conditions during transit in accordance with the following provisions and the Quality Agreement:

a. Dexcel is responsible for including data loggers on each shipment of Product.

b. Kitov shall ensure that every Distributor (A) removes the data loggers from the cartons and downloads the temperature data from the data loggers within one (1) Working Day from receipt of each shipment of Product, (B) within one (1) Working Day following the download of data, provides Dexcel with the results of the temperature data in the event of a temperature excursion, and (C) returns the data loggers to Dexcel within ten (10) Working Days of receipt of the shipment. Dexcel shall be entitled to charge Kitov the sum of $100 for each data logger which is lost or not timely returned to Dexcel."

8. Sections 4.1 and 4.2 of the Original Agreement are hereby deleted and the following new Sections 4.1 and 4.2 shall be substituted in lieu thereof:

"4.1 The Parties shall conclude a Quality Agreement (either together with a Distributor, or as a stand-alone Quality Agreement operating back-to-back with a quality agreement between Kitov and a Distributor) not later than ninety (90) days prior to the shipment of the initial order of the Product to Kitov (on behalf of each Distributor)."

"4.2 Kitov shall have the right (at reasonable intervals, with reasonable prior written notice and during normal business hours, and not more often than annually) to inspect Dexcel's manufacturing facilities used in the manufacture, storage, testing, and/or release for shipment of the Product. Subject to suitable confidentiality undertakings and with the prior written approval of Dexcel (which approval shall not be unreasonably withheld), Kitov may share the results of its audit and Dexcel's CAPA response with relevant Distributors, if required by GMP and/or the provisions of the relevant Quality Agreement."

9. Section 8.5.1 of the Original Agreement is hereby deleted and the following new Section 8.5.1 is substituted in lieu thereof:

"8.5.1 Dexcel agrees to defend, indemnify and hold Kitov and its Affiliates, and their respective officers, directors, and employees (collectively, the "Kitov Indemnitees") harmless from and against any Claims arising from (i) any product liability claims related solely to Dexcel's actions or negligence as the manufacturer of the Product, or (ii) any breach by Dexcel or its Affiliates of its representations, warranties, covenants, agreements or obligations under this Agreement, in all cases except to the extent such damages give rise to an indemnification claim by Dexcel under Section 8.5.2 below.

10. Section 8.5.2 of the Original Agreement is hereby deleted and the following new Section 8.5.2 is substituted in lieu thereof:

"8.5.2 Kitov agrees to defend, indemnify and hold Dexcel and its Affiliates, and their respective shareholders, officers, directors, and employees (collectively, the "**Dexcel Indemnitees**") harmless from and against any Claims arising from (i) the handling, possession, use, marketing, distribution, promotion or sale of any Product by Kitov, its Affiliates or any Distributors, including any of its or their employees or subcontractors or agents, following Delivery of the Product to Kitov, in any country, (ii) any breach by Kitov (including indirectly by its Affiliates or any of its Distributors), of its representations, warranties, covenants, agreements or obligations under this Agreement, (iii) any intellectual property infringement claims with respect to the Product or the Trademark; (iv) any product liability claims, whether arising out of warranty, negligence, strict liability (including design, warning or instruction claims) or any other product or quality based claims in relation to the Product; and (v) any demand for payment or demand for refund or indemnity by any Distributor against a Dexcel Indemnitee, in all cases except to the extent such damages give rise to an indemnification claim by Kitov under Section 8.5.1 above."

Signature page follows

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed through their duly appointed and authorized representatives as of the Amendment Effective Date.

DEXCEL PHARMA TECHNOLOGIES LTD

By:	/s/ Ilan Oren
Name:	Ilan Oren
Title:	C0-CEO
Date:	May 17, 2020

KITOV PHARMA LTD.

By:	/s/ Isaac Angel	/s/ Gil Efron
Name:	Isaac Israel	Gil Efron
Title:	CEO	Deputy CEO & CFO
Date:	May 12, 2020	

Exhibit 12.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Isaac Israel, certify that:

1. I have reviewed this annual report on Form 20-F of Purple Biotech 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(s) 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(s) 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, 2021

/s/ Isaac Israel
Isaac Israel
Chief Executive Officer

Exhibit 12.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gil Efron, certify that:

1. I have reviewed this annual report on Form 20-F of Purple Biotech 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(s) 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(s) 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, 2021

/s/ Gil Efron
Gil Efron
Chief Financial Officer

Exhibit 13.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Purple Biotech Ltd. (the "Company") hereby certifies, to such officer's knowledge that:

1. The Company's Annual Report on Form 20-F for the year ended December 31, 2020, to which this statement is furnished as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; 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, 2021

/s/ Isaac Israel
Isaac Israel
Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 13.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Purple Biotech Ltd. (the "Company") hereby certifies, to such officer's knowledge that:

1. The Company's Annual Report on Form 20-F for the year ended December 31, 2020, to which this statement is furnished as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; 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, 2021

/s/ Gil Efron
Gil Efron
Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 15.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Purple Biotech Ltd.

We consent to the incorporation by reference in registration statements No. 333-226195, No. 333-233795, No. 333-235327, No. 333-238229, and No. 333-239807 on Form F-3, registration statements No. 333-233793 and No. 333-235729 on Form F-1, and registration statements No. 333-211478, No. 333-218538, No. 333-230584 and No. 333-238481 on Form S-8. of Purple Biotech Ltd. of our report dated March 15, 2021, with respect to the consolidated statements of financial position of Purple Biotech Ltd. and its subsidiaries as of December 31, 2020 and 2019, the related consolidated statements of operations and other comprehensive loss, changes in equity and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes, and the effectiveness of internal control over financial reporting as of December 31, 2020, which report appears in the December 31, 2020 annual report on Form 20-F of Purple Biotech Ltd.

Our report refers to a change to the method of accounting for leases.

Somekh Chaikin
Member firm of KPMG International

Tel Aviv, Israel
March 15, 2021