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, 2023**

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)

Lior Fhima, Chief Financial Officer
4 Oppenheimer Street
Science Park
Rehovot 7670104, Israel
Tel: +972-3-933-3121; Fax: +972-3-5097196
(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: 252,379,218 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. ☐

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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:

- "Registrant," "Purple", "Purple Biotech", "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, (iii) its wholly owned subsidiary, FameWave, (iv) its wholly owned subsidiary, Immunorizon, and (v) its wholly owned subsidiary Purple Biotech GmbH, except where otherwise stated or where it is clear that the terms mean only Purple Biotech Ltd. exclusive of any subsidiaries,
- "TyrNovo" refers to TyrNovo Ltd., the majority owned subsidiary of Purple Biotech,
- "FameWave" refers to FameWave Ltd., the wholly owned subsidiary of Purple Biotech,
- "Immunorizon" refers to Immunorizon Ltd., the wholly owned subsidiary of Purple Biotech,
- "dollar", "US$" or "$" refer to U.S. dollars, the lawful currency of the United States of America,
- "Euro" or "€" refer to the Euro, the lawful currency of the European Union member states,
- "NIS" refers to the New Israeli Shekel, the lawful currency of the State of Israel,
- "IFRS" refers to the International Financial Reporting Standards as issued by the International Accounting Standards Board,
- "ordinary shares," "our shares" and similar expressions refer to the Registrant's ordinary shares, no par value per share,
- "ADSs" refers to the Registrant's American Depositary Shares,
- "Companies Law" refers to the Israeli Companies Law, 5759-1999,
- "Securities Act" refers to the Securities Act of 1933, as amended,
- "SEC" refers to the United States Securities and Exchange Commission,
- "NASDAQ" refers to The NASDAQ Capital Market, except where otherwise stated or where it is clear that the term means any of the NASDAQ exchanges, and
- "TASE" refers 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 ADS, 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 marketing 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.
"**CMC**"	Chemistry, manufacturing, and controls.
"Consensi"	An FDA approved fixed-dose combination drug treatment intended for the treatment of osteoarthritis pain and for hypertension, previously developed and commercialized by the Company. During 2021, the Company determined to discontinue operations related to Consensi.
"CROs"	Contract research organizations.
"**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.
"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.
"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.
"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.
"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.
"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, including the safety and efficacy of our therapeutic candidates, 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 the next stages of clinical trials, or to successfully complete our planned and ongoing 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 acquire or in-license additional therapeutic candidates, integrate acquired therapeutic candidates successfully into our business and to realize the anticipated benefits of acquisitions, such as our Immunorizon acquisition;
- a delay or rejection of an IND, NDA or BLA for one or more of our therapeutic candidates;
- our ability to regain and 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;
- our ability to establish collaborations for our therapeutic candidates;
- 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 on our industry; and
- the impact of the economic, 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 clinical-stage 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 therapeutic candidates for our future 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, and to develop, acquire and/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 current or future therapeutic candidates, seek regulatory approval that is a prerequisite to selling any product, attract development or commercial partners, and retain key personnel;
- Our long-term capital requirements are uncertain and subject to numerous risks;
- 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 therapeutic 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 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;
- Preclinical 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 and clinical studies, and then seeking to obtain regulatory approval, if such trials show that our therapeutic candidates are safe and effective;
- 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 and/or commercialize such therapeutic candidates, 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. 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 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 current business model is based largely upon the development or acquisition and commercialization of new combination products and new therapeutic candidates that may have not yet been administered to humans or have limited history of treatment with 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 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 with quality standards for our therapeutic candidates, which may endanger our clinical trial participants and/or fail to meet established deadlines for the completion of such studies and trials;

- 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, preclinical, clinical development and commercialization of our therapeutic candidates could be delayed;

- We rely on third-party contract vendors to manufacture and supply us with API/Drug Product that is compliant with the International Conference of Harmonization Q7 guidance and other applicable laws and regulations, in the quality and quantities we require on a timely basis;

- 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, our tribody platform's leading therapeutic candidate IM1240 or any other therapeutic candidates we may develop or acquire in the future;

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

- 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 will obtain (if any), and our business would be seriously harmed;

- The manufacture of our therapeutic 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 inability to maintain a commercially viable cost structure;

- We may depend on a partner to conduct clinical trials with CM24, NT219 and/or other therapeutic candidates, and we may enter into future collaboration agreements with collaboration partners to develop and conduct clinical trials with, obtain regulatory approvals for, and to 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 partners, which we may not be able to engage in a timely manner, if 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;

- Because each of CM24, NT219 and our tribody platform with its leading candidate IM1240 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 these therapeutic candidates;

- If we fail to comply with any obligations under our in-license agreements with Yissum Research and Development Company ("Yissum") and/or Tel Hashomer – Medical Research Infrastructure and Services Ltd. ("THM") or any future license agreement, or disputes arise with respect to those agreements, it could have a negative impact on our intellectual property rights and we could lose our rights to NT219 and/or CM24 or any further therapeutic candidates, which could have a material adverse effect on our business, financial condition and results of operations.

- 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;

- We may not meet the continued listing requirements of NASDAQ, which could result in a delisting of the ADSs from NASDAQ.

- Our business and operations may be materially adversely affected in the event of computer system failures or security or breaches due to cyber-attacks or cyber intrusions, including ransomware, phishing attacks and other malicious intrusions;

- 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 claims or other legal challenges could have a material adverse effect on our business, results of operations and on our 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 property rights may lead us to lose market share and could have an adverse effect on our business, results of operations and financial condition; and

- We conduct our operations in Israel. Conditions in Israel, including the ongoing attacks by Hamas and other terrorist organizations from the Gaza Strip that were initiated in October 2023 and Israel's war against them, may affect 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. [Reserved]

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 clinical-stage 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 clinical-stage pharmaceutical company, and we are focused on the development and commercialization of innovative pharmaceutical drugs. We currently have two oncology therapeutic candidates in clinical trials, NT219 and CM24, neither of which has been approved for marketing and they are not being sold, marketed or commercialized, and a preclinical tribody platform with its leading therapeutic candidate, IM1240, which we acquired in connection with our acquisition of Immunorizon in February 2023. 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 these therapeutic candidates, 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, 2023, of approximately $137.5 million as a result of revenue and cost of goods, 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, tribody platform with its leading therapeutic candidate IM1240 or other therapeutic candidates that we may develop, in-license, 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, in-license, 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. We may be unable to achieve any or all these goals with regard to NT219, CM24, tribody platform with its leading therapeutic candidate IM1240 or any other therapeutic candidates that we may develop, in-license, or acquire in the future. 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 therapeutic candidates for our future 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 our NT219 and CM24 therapeutic candidates and our tribody platform with its leading therapeutic candidate IM1240, as well as to developing, gaining regulatory approval and commercializing Consensi (prior to discontinuing related operations during 2021); research and development; raising capital; and recruiting scientific, CMC, regulatory and management personnel and third-party partners. To date, the only revenue we have received has been the initial milestone payments in connection with commercialization agreements for Consensi, which were terminated in 2021. We may not be able to commercialize or obtain regulatory approval for our NT219, CM24 and our tribody platform with its leading therapeutic candidate IM1240 therapeutic candidates or any additional therapeutic candidates we may develop, in-license and/or acquire in the future. Our future growth and success depend upon our ability to continue funding the development of our therapeutic candidates and on the successful commercialization of such therapeutic candidates. If we are unable to obtain regulatory clearances or approvals for our therapeutic candidates and future products, our ability to gain any revenues and to achieve profitability 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 or in-license 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, and to develop, acquire and/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 current or future therapeutic candidates, seek regulatory approval that is a prerequisite to selling any product, attract development or commercial partners and retain key personnel.

We will need to continue to expend substantial funds in research and development, including CMC, preclinical and clinical trials of our NT219, CM24 and our tribody platform with its leading therapeutic candidate IM1240 therapeutic candidates, as well as to acquire or in-license additional therapeutic candidates. We plan to fund our future operations through the out-licensing and/or commercialization of our therapeutic candidates and by raising additional capital through 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.

On June 9, 2021, we entered into an open market sale agreement (the "Sales Agreement"), with Jefferies LLC ("Jefferies"), for the sale of ADSs, representing our ordinary shares. In accordance with the terms of the Sales Agreement, we may offer and sell, from time to time, ADSs through an "at-the-market" equity offering program ("ATM program"), with Jefferies acting as our agent. We originally filed a prospectus for a $50.0 million ATM program, but the aggregate offering price was subsequently reduced to $21.0 million on March 23, 2022, and to $3.0 million on October 17, 2023. Any future sales of ADS under the Sales Agreement could result in substantial dilution to existing shareholders. As of March 5, 2024, we have sold approximately 2,217,325 ADSs for total gross proceeds of $4.0 million under the Sales Agreement.

On December 8, 2022, we filed a registration statement on Form F-3 with the SEC utilizing a "shelf" registration process, under which we may offer and sell, from time to time in one or more offerings, up to an aggregate $200,000,000 of ADSs (representing our ordinary shares), ordinary shares, preferred shares, warrants, overallotment purchase rights, subscription rights, units and/or capital notes. In October 2023, we completed a $5 million registered direct offering with an institutional investor for the purchase and sale of 2,430,000 ADSs and pre-funded warrants to purchase up to 1,917,827 ADS, and, in a concurrent private placement, unregistered warrants to purchase up to 4,347,827 ADSs, which are exercisable immediately.

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

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, we will need to raise substantial additional funds to develop and/or commercialize our therapeutic candidates and to develop, 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, in-license, or develop in the future;
- our ability to successfully out-license and/or commercialize our oncology therapeutic candidates, or any other therapeutic candidates that we may acquire, in-license, or develop in the future, including securing commercialization agreements with third parties and favorable pricing and market share;
- 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 and maintaining regulatory approval of our oncology therapeutic candidates or any other therapeutic candidates that we may acquire, in-license, or develop in the future and addressing regulatory and other issues that may arise post-approval for such oncology therapeutic candidates;
- 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;
- 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 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; and
- sufficient coverage and reimbursement by third-party payers for our therapeutic candidates.

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, Operations 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. Many 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 our therapeutic candidates.

Our therapeutic 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 therapeutic 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 therapeutic 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.

To date, we have not marketed, distributed or sold any oncology drug product. 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. 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.

Preclinical 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 and clinical studies, 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 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. Implementation of CMC and the 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, CMC, the preclinical studies and/or clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates.

In connection with CMC and the 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, and shortages of combination drugs used in our clinical studies.
- 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;
- 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;
- 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;
- our therapeutic candidates may not be reimbursed under different healthcare programs such as Medicare, Medicaid or private health insurance programs;
- 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 therapeutic 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, and/or commercialize such therapeutic candidates, or otherwise raise substantial additional capital, we will likely need to alter our development and any commercialization plans.

Our drug development programs, mainly 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 (including by way of out-licensing) to assist us in furthering development and potential commercialization of our therapeutic candidates, in some or all jurisdictions. We may not be successful in such collaborations with such third parties on acceptable terms, or at all. In addition, if we fail to negotiate and maintain suitable development (such as out-licensing) 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 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, 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 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. Our collaborative arrangements may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. 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 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;
- we may suffer losses due to our collaborators' failure to perform their duties and we may not be able to be reimbursed by our collaborators for such losses;
- 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 therapeutic candidates that may have not yet been administered to humans or have limited history of treatment with 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 currently have two oncology therapeutic candidates in clinical trials, NT219 and CM24, both of which have limited safety and efficacy data for treatment in humans. The previous owners of CM24 conducted the first human clinical trials for this therapeutic candidate, which were initiated in 2015, and discontinued in 2017. In March 2021, we initiated a Phase 1b/2 clinical trial evaluating CM24, in advanced cancer patients, with expansion cohorts in subjects with non-small cell lung cancer (NSCLC) and pancreatic cancer, and in August 2022, we advanced the trial to a randomized, controlled, open label, multicenter Phase 2 study in subjects with metastatic pancreatic cancer (PDAC) as a second line treatment to evaluate the safety and tolerability of CM24 in combination with nivolumab and chemotherapy as compared to standard of care chemotherapy. In the second half of 2020, we commenced a first in human phase 1/2 study of NT219, as a single agent in patients with recurrent and/or metastatic advanced solid tumors, followed by a dose escalation phase of NT219 in combination with cetuximab for the treatment of recurrent and/or metastatic squamous cell carcinoma of the head and neck (SCCHN) and colorectal adenocarcinoma. In February 2024, we determined the recommended Phase 2 dose (RP2D) for NT219 in combination with cetuximab in the treatment of head and neck cancer based on the Phase 1/2 dose escalation study to be 100mg/kg. We plan to commence a phase 2 study of NT219 at its RP2D level in combination with cetuximab in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck in the first half of 2024. Further, our third therapeutic candidate, IM1240, which is the leading therapeutic candidate of our tribody platform that we acquired in connection with our acquisition of Immunorizon in February 2023, is in preclinical development and no human clinical trials have been conducted for this therapeutic candidate. We cannot be certain whether any of our therapeutic candidates 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 other cancer treatments, or any other therapeutic candidate that we may develop or acquire in the future to be superior to the then 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 therapeutic candidates could have an adverse effect on our business, financial condition and results of operations.

Further, as part of our strategy for growth, we may consider the acquisition of additional therapeutic candidates at various stages of development and in a variety of therapeutic areas, and we may 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. For example, our ability to successfully transition and integrate the acquired Immunorizon may be critical for our future growth and financial stability, and given the challenges involved with the development of a biological product and the financial challenges, we may not be able to realize the anticipated benefits of the acquisition, which may materially adversely affect our growth and future operating results as well as our financial condition. 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 therapeutic 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 to a large degree we rely on third parties, such as contract manufacturing organizations, CROs, 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, CROs 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 CMC and the 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, preclinical, clinical development and commercialization of our therapeutic candidates could 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 entirely 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 API/Drug Product to be compliant with the International Conference of Harmonization Q7 guidance and other applicable laws and regulations, in the quality and quantities we require on a timely basis.

We currently do not manufacture any API/Drug Product ourselves. Instead, we rely on third-party vendors for the manufacture and supply of our APIs/Drug Products that are used to formulate our oncology therapeutic candidates. While there are many potential API/Drug Product 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 developing or conducting clinical trials for our current therapeutic candidates, NT219, CM24 and IM1240, 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/Drug Product in the market, we have not conducted extensive audits and investigations into the quality or availability of their APIs/Drug Products. In addition, we may acquire therapeutic candidates which already have long term commitments to a specific API/Drug Product supplier. As a result, we can provide no assurances that supply sources will not be interrupted from time to time. Changing API/Drug Product manufacturers or suppliers or finding and qualifying new API/Drug Product manufacturers or suppliers can be costly and take a significant amount of time. Many APIs/Drug Products 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/Drug Products, we may not be able to 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, our tribody platform's leading therapeutic candidate IM1240 or any other therapeutic candidates we may develop or acquire in the future.

To date, our NT219, CM24 and IM1240 therapeutic candidates have 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 to successfully 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 to successfully 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 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 oncology therapeutic candidates when we initiate their clinical trials. We and our third-party contract manufacturers may not be able to comply with applicable laws, regulations and guidelines. We and our third-party contract 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 contract 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 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, our clinical trials may be placed on hold, we could lose the FDA and/or other regulatory agencies' approval(s) we will obtain (if any), and our business would be seriously harmed.

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 in the future 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. 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 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 in other civil or criminal sanctions, including fines and penalties.

Regulatory approval of our oncology therapeutic candidates (if any) will be 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 such product candidates 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. Marketing or commercializing of therapeutic candidates to treating a new symptom or indication, that was not approved by the FDA or similar foreign authorities 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 will rely on physicians to prescribe and administer our therapeutic candidates (if approved for marketing by the FDA or similar foreign authorities) or as the product labeling directs and for the indications described on the labeling. To the extent any physicians prescribe such product to patients for off-label uses, or the use of such products depart from the approved use, this may increase the risk of injury or other adverse events to the patients and the risk of filing product liability claims 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, any off-label use may not effectively treat the conditions associated with such 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 our therapeutic candidates (if approved for marketing by the FDA or similar foreign authorities) 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 our therapeutic candidates 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 our therapeutic candidates 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 requires that our and our future 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.

We may encounter substantial delays in the clinical trials for our therapeutic candidates, or we may not be able to conduct their trials on the timelines we expect, or we may not be able to complete them at all.

Clinical testing is expensive, time-consuming, and subject to uncertainty. Currently, two of our therapeutic candidates are in clinical trials, NT219 and CM24, and we cannot guarantee that any of these therapeutic candidate's and/or future therapeutic candidate's clinical studies will be initiated or conducted as planned, or completed on schedule, if at all. We intend to continue our clinical testing of CM24 and 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 clinical studies for any of our therapeutic candidates 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;
- the shortage of staff in the clinical sites;
- imposition of a temporary or permanent clinical hold by regulatory agencies;
- delays in recruiting suitable patients to participate in clinical studies for NT219, CM24 or future therapeutic candidates;
- 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 and/or future therapeutic candidates being greater than we anticipate;
- management's decision to allocate internal resources to other projects;
- clinical studies of CM24, NT219 and/or future therapeutic 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 therapeutic candidates or approved drugs for use in clinical studies or the inability to do any of the foregoing, including any quality issues associated with contract manufacturers.

We also may conduct clinical research in collaboration with other biotechnology and biologics entities in which we combine CM24, NT219 and/or other or future therapeutic candidates 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, or a shortage in the availability of such collaborators' drug products. These combination therapies will require additional testing and clinical trials, will require additional FDA regulatory approval, and will increase our future expenses.

In addition, if we make manufacturing or formulation changes to CM24, NT219 and/or other or future therapeutic candidates, 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.

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 therapeutic candidates as projected or may not conduct them successfully.

We expect to rely on medical institutions, academic institutions, or CROs to conduct, supervise, or monitor some or all aspects of clinical trials involving our therapeutic candidates. 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 epidemics, endemics or pandemics, such as the COVID-19 endemic, on the ability of patients to visit the testing sites and the effect of the disease on potential patients who contracted the disease.

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 may 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.

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 our therapeutic candidates.

We may depend on a partner to conduct clinical trials with CM24, NT219 and/or other therapeutic candidates, and we may enter into future collaboration agreements with collaboration partners to develop and conduct clinical trials with, obtain regulatory approvals for, and to 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 partners, which we may not be able to engage in a timely manner, if 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 and supply agreement with Bristol Myers Squibb Company (NYSE:BMY) for a phase 1/2 study of CM24 in combination with a programmed cell death protein 1 (PD-1) antibody nivolumab, and an expansion study to also evaluate CM24 and nivolumab, together with nab-paclitaxel, in patients with pancreatic cancer. We initiated the phase 1b/2 portion of the phase 1/2 study in March 2021 and in August 2022, we initiated a randomized, controlled, open label, multicenter Phase 2 portion of this study in subjects with metastatic pancreatic cancer (PDAC) as a second line treatment to evaluate the safety and tolerability of CM24 in combination with nivolumab and chemotherapy and in December 2023, we enrolled the last patient for this Phase 2 study. We rely and may in the future continue to rely on our collaboration partners to develop, supply, conduct clinical trials, and/or commercialize our therapeutic candidates and approved products we may market in the future, if any. 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 obtain regulatory approval for, and 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. Any such termination of any current or future agreement with a collaboration partner could have a material adverse effect on our business, financial position and results of operations.

The manufacture of our therapeutic 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 inability to maintain a commercially viable cost structure.

NT219 is a small molecule chemical compound and CM24 and our tribody platform with its leading therapeutic candidate IM1240 are biologic compounds, and the process of manufacturing each is complex, highly regulated and subject to multiple risks. Even minor deviations from normal manufacturing processes for each of NT219, CM24 and our tribody platform with its leading therapeutic candidate IM1240 and/or any future therapeutic candidate 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 our therapeutic candidates' preclinical development, clinical development and/or commercialization plans. We may ultimately be unable to reduce the cost of goods for each of our therapeutic candidates to levels that will allow for an attractive return on investment if and when those therapeutic candidates are commercialized.

Because each of CM24, NT219 and our tribody platform with its leading therapeutic candidate IM1240 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 these therapeutic candidates.

There is no assurance that the approaches offered by CM24, NT219 or our tribody platform with its leading candidate IM1240 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 each of CM24, NT219 and our tribody platform with a leading therapeutic candidate IM1240 represents a new approach 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 our therapeutics candidates 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 these therapeutic candidates, and the actual cost to manufacture these therapeutic products could materially and adversely affect the commercial viability of these products. Our goal is to reduce the cost of manufacturing our therapeutic candidates. However, unless we 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 our therapeutic candidates based upon this approach or find suitable and economical sources for materials used in the production of these therapeutic candidates, these therapeutic candidates will not become profitable.

Our 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 our therapeutic candidates' based therapies 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 in-license agreements with Yissum and/or THM or any future license agreement, or disputes arise with respect to those agreements, it could have a negative impact on our intellectual property rights and we could lose our rights to NT219 and/or CM24 or any future therapeutic candidate, which could have a material adverse effect on our business, financial condition and results of operation.

We are a party to a license agreement with each of Yissum, the technology transfer company of the Hebrew University of Jerusalem, and THM, pursuant to which we license rights to our therapeutic candidates NT219 and CM24, respectively. These license agreements 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 us 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 our licensors and collaborators;
- the scope and duration of our payment obligations;
- our ability to further license the technology to third parties;
- 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 or if other events occur that are not within our control, these agreements may be terminated or the scope of our rights under them may be reduced, we could lose the rights to our therapeutic candidates NT219 and CM24 or any other therapeutic candidate we license, and we might be unable to develop, manufacture or market any product that is licensed under these agreements, could experience delays in developing or commercializing these therapeutic candidates or incur additional costs, any of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, we may have disputes over intellectual property rights related to our therapeutic candidates developed under service agreements or material transfer agreements with third parties. Such third parties may claim rights to certain know-how or intellectual property that may require us to enter into license agreements with such parties and pay royalties for such rights or to engage in legal proceedings with these parties.

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 (through the acquisition of a company or a company's assets), or in-licensing of therapeutic candidates, our shareholders may 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 or new product. 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 or in-licensing agreement. 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.

For example, in February 2023 we completed the acquisition of 100% of the shares of Immunorizon, which is developing potential multi-specific T and NK cell engager oncology therapies that selectively activate the immune response within the tumor microenvironment (TME), in exchange for an aggregate upfront payment of $3.5 million in cash and an aggregate $3.5 million in ADSs (or 2,215,190 ADSs representing ordinary shares) and additional long-term milestones set at an aggregate amount of $94 million, with royalties out of net sales. While we have completed the process for the integration of Immunorizon's technology platform and allocated resources to the ongoing research and development related to the platform, given the challenges involved with the development of a biological product and the financial challenges, we may not be able to realize the anticipated benefits of the acquisition, which may materially adversely affect our growth and future operating results as well as our financial condition.

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

We own the rights to our therapeutic candidates, each of which was acquired by us from a third-party: NT219 (acquired in connection with the acquisition of the majority shareholdings of TyrNovo in 2017), CM24 (acquired in connection with the acquisition of FameWave in 2020) and tribody platform (acquired in connection with the acquisition of Immunorizon in February 2023). 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.

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 every member 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. If we purchase or in-license new products or product candidates, we may need to expand our qualified personnel to advance the development and commercialization of such products. In addition, if we elect to independently commercialize any therapeutic candidate, we will need to expand our marketing and sales capabilities. 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. 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 (the "Board") and, in certain instances, our shareholders. 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 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, export and import of pharmaceutical products, 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.

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

TyrNovo's technologies, including NT219, were developed, in part, with grants from the Israel Innovation Authority, or IIA (formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry) in the aggregate amount of approximately NIS 5.5 million (or approximately $1.5 million). As of December 31, 2023, TyrNovo had not paid any royalties to the IIA and had a contingent obligation to the IIA (including interest) of $2.3 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 IIA grants are 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, in whole or in part, by the IIA, at rates which are determined under the IIA's rules and guidelines (generally of 3% to 6% on sales of products or services developed under the approved programs, 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 payments; however, other restrictions under the Innovation Law continue to apply, as described below.

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 received the IIA's approval for the production of NT219's API and final product by certain third-party manufacturers outside of Israel in consideration for (among other things) the future payment of increased royalties as stipulated under the IIA's rules and guidelines. 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 also 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. 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.

We have in the past, and may in the future, become subject to litigation or claims arising in or outside the ordinary course of business that could negatively affect our business operations and financial condition.

We have in the past, and may in the future, become subject to litigation or claims arising in or outside the ordinary course of business (other than intellectual property infringement actions) that could negatively affect our business operations and financial condition, including securities class actions and shareholder derivative actions, both of which are typically expensive to defend. Such claims and litigation proceedings may be brought by third parties, including our competitors, advisors, service providers, partners or collaborators, employees, and governmental or regulatory bodies. For information on past legal proceedings, please see "Item 8. Financial Information – A. Financial Statements and Other Financial Information – Legal Proceedings." Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. We may not be able to determine the amount of any potential losses and other costs we may incur due to the inherent uncertainties of litigation and settlement negotiations. In the event we are required or decide to pay amounts in connection with any claims or lawsuits, such amounts could be significant and could have a material adverse impact on our liquidity, business, financial condition and results of operations. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter could materially affect our future operating results, our cash flows or both. 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.

Risks Related to Our Industry

Even if our oncology therapeutic candidates or any other therapeutic candidate that we develop or in-license in the future receive regulatory approval, they may not become or remain commercially viable products.

In the event that 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, 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.

If we are unable, either on our own or through third parties, to manufacture, commercialize and market our oncology therapeutic candidates or any other therapeutic candidates that we may develop or acquire in the future when planned, or develop or acquire commercially viable therapeutic candidates, we may not achieve any market acceptance or generate revenue.

The markets for 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 our 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 therapeutic candidates, some of them are in a more progressed stage of development than us and may reach the market before we do.

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 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 NT219, CM24, our tribody platform with its leading therapeutic candidate IM1240 or other therapeutic candidates that we may develop or in-license 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.

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 oncology therapeutic candidates to receive widespread acceptance.

If third-party payers do not adequately reimburse customers for our oncology therapeutic candidates, if approved for marketing in the U.S. or other markets, 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 oncology therapeutic candidates, if approved, from governmental and/or other third-party payers, both in the U.S. and in foreign markets. 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.

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 oncology therapeutic candidates, if approved. We believe that legislation that reduces reimbursement for our oncology therapeutic candidates, if approved, could adversely impact how much or under what circumstances healthcare providers will prescribe or administer 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 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.

On March 23, 2010, President Obama signed the "Patient Protection and Affordable Care Act" (P.L. 111-148) (the "ACA") and on March 30, 2010, he signed the "Health Care and Education Reconciliation Act" (P.L. 111-152), collectively commonly referred to as the "Healthcare Reform Law." The Healthcare Reform Law included a number of new rules regarding health insurance, the provision of healthcare, conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients, and other healthcare policy reforms. Through the law-making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the U.S., including changes made to extend medical benefits to certain Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and drugs, and imposing additional taxes, fees, and rebate obligations on pharmaceutical and medical device companies). This legislation was one of the most comprehensive and significant reforms ever experienced by the U.S. in the healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law's provisions were designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. This environment 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 surrounding pharmaceuticals which could result in lower pricing and/or reduced market acceptance for any drug products we may commercialize in the U.S. in the future. At this stage, it is difficult to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the ACA and judicial challenges have continued for over a decade. However, as of the Supreme Court's ruling ordering the dismissal of, arguably, the most promising case challenging the ACA to-date on June 17, 2021, it appears that the ACA will remain in-effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business. The Biden administration also introduced various measures in 2021 focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, in July 2021, the Biden administration released an executive order entitled, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response, on September 9, 2021, HHS released a "Comprehensive Plan for Addressing High Drug Prices" that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. And, in August 2022, the Inflation Reduction Act ("IRA") was signed into law, which will, among other things, allow U.S. Department of Health and Human Services ("HHS") to negotiate the selling price of certain drugs and biologics that the Centers for Medicare & Medicaid Services ("CMS") reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2023, the IRA also began penalizing drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. Additionally, in December 2023, the Biden-Harris Administration announced further related initiatives under the IRA to lower prescription costs and increase competition with help from HHS, the DOJ, and the FTC.

There is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the U.S. or the effect of any future legislation or regulation. However, in early January 2024, the FDA did approve a plan from Florida to import low-cost drugs from Canada. Furthermore, we cannot predict what actions the Biden administration will implement in connection with the Health Reform Law. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the U.S. in the future, as applicable.

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 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 any product candidates for which we obtain FDA approval. The applicable healthcare laws to which we have been and/or may be subject 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, as defined by such law, certain other healthcare professionals, and teaching hospitals and ownership and investment interests held by physicians and 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 prior and/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 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 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 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 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 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.

Unfavorable macroeconomic conditions and other adverse macroeconomic factors could adversely affect our business, financial condition, cash flow or results of operations.

Unfavorable macroeconomic conditions and other adverse macroeconomic factors have resulted, among other matters, in tightening in the debt and equity markets, and high levels of inflation. For example, tightening of the equity markets, makes it more difficult to raise capital at a reasonable valuation or at all. In addition, the U.S. Bureau of Labor Statistics has reported for the period from January 2022 to January 2023, the Consumer Price Index for All Urban Consumers rose 6.4 percent, and from January 2023 to January 2024, the Consumer Price Index for All Urban Consumers rose 3.1 percent. If the inflationary pressure continues for a prolonged period, it may continue to result in increased costs of labor, cost of clinical trials, and costs of manufacturing which could adversely affect our results of operations. Furthermore, during 2022 and 2023 there was a significant increase in interest rates that impacted the cost of debt, liquidity and valuations of companies and other assets. Our results of operations could be adversely affected by general conditions in the global and local macroeconomic economy conditions affecting the 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.

Our business and operations may be materially adversely affected in the event of computer system failures or security or breaches due to cyber-attacks or cyber intrusions, including ransomware, phishing attacks and other malicious intrusions.

In recent years, cybersecurity threats have become a greater risk and focus for companies. In particular, ransomware attacks, where a hacker locks and threatens to delete or disclose the victim's data unless a ransom is paid, has become a major risk. We and those of our third-party contract manufacturers and other third parties on which we rely are at risk of cyber-attacks or cyber intrusions via the Internet, computer viruses, break-ins, malware, ransomware, phishing attacks, hacking, denial-of-service attacks or other attacks and similar disruptions from the unauthorized use of, or access to, computer systems (including from internal and external sources). These types of incidents continue to be prevalent and pervasive across industries, including in our industry. In addition, we expect information security risks to continue to increase due to the proliferation of new technologies and the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign state actors.

Despite the implementation of security measures, our internal computer systems, and those of our third-party contract manufacturers and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, cyber intrusions, natural disasters, fire, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, access to our clinical data, we could incur liability and the further development of our therapeutic candidates could be delayed.

Increasing scrutiny of, and evolving expectations for, sustainability and environmental, social, and governance ("ESG") initiatives could increase our costs or otherwise adversely impact our business.

Public companies are facing increasing scrutiny related to ESG practices and disclosures from certain investors, capital providers, shareholder advocacy groups, other market participants and other stakeholder groups. For example, certain institutional and individual investors have requested various ESG-related information and disclosures as they increasingly incorporate ESG criteria in making investment and voting decisions. With this increased focus, public reporting regarding ESG practices is becoming more broadly expected. Such increased scrutiny may result in increased costs, enhanced compliance or disclosure obligations, or other adverse impacts on our business, financial condition or results of operations. If our ESG practices and reporting do not meet investor or other stakeholder expectations, which continue to evolve, we may be subject to investor or regulator engagement regarding such matters. In addition, new sustainability rules and regulations have been adopted and may continue to be introduced in various states and other jurisdictions. For example, the SEC has published proposed rules that would require companies to provide significantly expanded climate-related disclosures in their periodic reporting, which may require us to incur significant additional costs to comply and impose increased oversight obligations on our management and Board. Our failure to comply with any applicable rules or regulations could lead to penalties and adversely impact our reputation, access to capital and employee retention. Such ESG matters may also impact our third-party contract manufacturers and other third parties on which we rely, which may augment or cause additional impacts on our business, financial condition, or results of operations.

Risks Related to Intellectual Property

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 claims or other legal challenges could have a material adverse effect on our business, results of operations and on our 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 impossible 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 attention and 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.

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 property rights may lead us to lose market share and could have an adverse effect on our business, results of operations and financial condition.

Our success depends, in part, on our ability, and the ability of our 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 and biopharmaceutical companies. 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 intend to seek regulatory approval to market our oncology therapeutic candidates in a number of foreign countries. Our oncology therapeutic candidates are not protected by patents in certain countries, 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 oncology 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 less protected by patents in China than in the U.S., 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 all, or certain, 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

We conduct our operations in Israel. Conditions in Israel, including the ongoing attacks by Hamas and other terrorist organizations from the Gaza Strip that were initiated in October 2023 and Israel's war against them, may affect our business, results of operations, and financial condition.

Because we are incorporated under the laws of the state of Israel and our operations are conducted in Israel, our business and operations are directly affected by economic, political, geopolitical and military conditions in Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries and terrorist organizations active in the region. These conflicts have involved missile strikes, hostile infiltrations and terrorism against civilian targets in various parts of Israel, which have negatively affected business conditions in Israel.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict.

Any hostilities involving Israel, 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. While five study sites out of 27 total study sites for the ongoing studies for CM24 and NT219 are located in Israel, we have not yet experienced any material interruptions or delays with respect to such studies, and we believe the study sites in Israel have sufficient supply of the therapeutic candidates to continue the studies, as applicable. Both CM24 and NT219 are manufactured by service providers outside of Israel. Most of our research and development work is being conducted by third-party entities outside of Israel. However, a prolonged conflict with Hamas may cause disruptions or delays to our study sites located in Israel, as a result of shortage of staff at such study sites, resulting in an adverse effect on our business, financial condition and results of operation.

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 or, if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business.

Parties with whom we may do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. The conflict situation in Israel 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 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.

There have been travel advisories imposed as related to travel to Israel, and restriction on travel, or delays and disruptions as related to imports and exports may be imposed in the future. An inability to receive supplies and materials, shortages of materials or difficulties in procuring our materials, among others, may adversely impact our ability to commercialize and manufacture our product candidates and products in a timely manner. This could cause a number of delays and/or issues for our operations, including delay of the review of our product candidates by regulatory agencies, which in turn would have a material adverse impact on our ability to commercialize our product candidates.

Additionally, all members of our management team and all of our employees are located and reside in Israel. Shelter-in-place and work-from-home measures, government-imposed restrictions on movement and travel and other precautions that may be taken to address the ongoing conflict may temporarily disrupt our management and employees' ability to effectively perform their daily tasks.

The Israel Defense Force (the "IDF"), the national military of Israel, is a conscripted military service, subject to certain exceptions. Several of our employees and management members are subject to military service in the IDF and have been and may be called to serve. There may be further or longer military reserve duty call-ups in the future, which may affect our business due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, for example, which may have unintended negative effects and adversely impact our results of operations, liquidity or cash flows.

It is currently not possible to predict the duration or severity of the ongoing conflict or its effects on our business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing, and could disrupt our business and operations, interrupt our sources and availability of supply and hamper our ability to raise additional funds or sell our securities, among others.

Any armed conflicts, terrorist activities or political instability in the region would likely negatively affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital.

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. In addition, it may 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 or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws against us or our non-U.S. officers and directors on the grounds that Israel is not 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.

Additionally, Israeli courts might not enforce judgments obtained in the United States against us or our non-U.S. directors and executive officers, which may make it difficult to collect on judgments rendered against us or our non-U.S. officers and directors by either a U.S. or foreign court. Moreover, an Israeli court will not enforce a non-Israeli judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases), if its enforcement is likely to prejudice the sovereignty or security of the State of Israel, if it was obtained by fraud or in the absence of due process, if it is at variance with another valid judgment that was given in the same matter between the same parties, or if a suit in the same matter between the same parties was pending before a court or tribunal in Israel at the time the foreign action was brought.

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, to the fullest extent permitted by applicable law, to the extent that these liabilities are not covered by insurance. The total amount of the indemnity will not exceed 25% of our then consolidated shareholders' equity, per our most recent audited or reviewed consolidated 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, the Atzmon Claim described in "Item 8. Financial Information – A. Financial Statements and Other Financial Information – Legal Proceedings", or other claims which may be filed against our directors and officers, 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 "*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 claims or other legal challenges could have a material adverse effect on our business, results of operations and on our financial condition*" under the risk factor section titled "Risks Related to 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.

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. These provisions include matters in connection with the election and removal of directors, such as our staggered Board, the right of our Board to appoint additional directors to fill vacancies on the Board, the size of our Board, the terms of office of our directors and the special majority required to amend such provision in our amended and restated articles of association.

Further, under 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, 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, 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 companies, 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. See *"We can issue non-voting senior preferred shares without shareholder approval, which could adversely affect the rights of holders of ordinary shares."*

These and other similar provisions could delay, prevent or impede an acquisition of us by a third-party or our merger with another company, or an acquisition of a significant portion of our shares, and may make it more difficult for our shareholders to elect different individuals to our Board, even if doing so would be considered to be beneficial by some of our shareholders, and may limit the price that investors may be willing to pay in the future for our ordinary shares.

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 sales or 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 and inflation. 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, other than with respect to plaintiffs or a class of plaintiffs which may be entitled to assert a cause of action arising under the Securities Act of 1933 in the courts of the State of Israel, the federal district courts of the United States for the District of New York shall otherwise 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 is 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;
- the outcome of any litigation and other legal proceedings;
- changes in government regulations or patent decisions;
- developments by our current or potential development and commercialization partners; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance and including the impact of Israel's war with Hamas and other militant groups and the ongoing effects of the COVID-19 endemic.

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 have been very volatile and have experienced significant price and volume fluctuations for reasons often unrelated to the operating performance of any one company. These fluctuations may be attributed, among other reasons, to the COVID-19 endemic or more recently to general global economic environment and the instability in markets. 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 "*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 claims or other legal challenges could have a material adverse effect on our business, results of operations and on our financial condition*."

A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price ADSs or ordinary shares.

Future sales of our ordinary shares or ADSs, or securities convertible into our ordinary shares or ADSs, or the perception that future sales may occur, could reduce the market price of our ordinary shares and ADSs.

As of March 5, 2024, we had an aggregate of 265,584,738 issued and outstanding ordinary shares (including 1 dormant ordinary share held in treasury), no non-voting senior preferred shares, outstanding non-listed warrants to purchase 8,342,532 ADSs (representing 83,425,320 ordinary shares) issued to investors, underwriters and placement agents as part of a number of public and registered direct offerings by us and 24,962,206 outstanding options and restricted share units ("RSUs"). In the future, we may issue additional ordinary shares, ADSs or other equity or debt securities exercisable or convertible into ordinary shares or ADSs.

On June 9, 2021, we entered into the Sales Agreement with Jefferies for the sale of ADSs, pursuant to which we may offer and sell ADSs from time to time under our ATM program, with Jefferies acting as our agent. We originally filed a prospectus for a $50.0 million ATM program, but the aggregate offering price was subsequently reduced to $21.0 million on March 23, 2022, and to $3.0 million on October 17, 2023. As of March 5, 2024, we have sold approximately 2,217,325 of our ADSs for total gross proceeds of $4.0 million under the Sales Agreement.

On December 8, 2022, we filed a registration statement on Form F-3 with the SEC utilizing a "shelf" registration process, under which we may offer and sell, from time to time in one or more offerings, up to an aggregate $200,000,000 of ADSs (representing our ordinary shares), ordinary shares, preferred shares, warrants, overallotment purchase rights, subscription rights, units and/or capital notes. In October 2023, we completed a $5 million registered direct offering with an institutional investor for the purchase and sale of 2,430,000 ADSs and pre-funded warrants to purchase up to 1,917,827 ADS, and, in a concurrent private placement, unregistered warrants to purchase up to 4,347,827 ADSs, which are exercisable immediately. In November 2023, we filed a registration statement on Form F-1 with the SEC, under which the investor and placement agent in the offering may resell from time to time the ADSs issuable upon exercise of the unregistered warrants issued to them in the offering. If these registered ADSs issuable upon exercise of the unregistered warrants are sold to the public, the market price of our ADSs may decline.

Any future sales by us or our shareholders of a substantial number of our ordinary shares or ADSs, or securities convertible into our 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 warrants or options, the vesting or RSUs or the conversion of convertible securities, may cause the market price of our ordinary shares or ADSs or other listed securities to decline.

We may not meet the continued listing requirements of NASDAQ, which could result in a delisting of the ADSs from NASDAQ.

The ADSs are listed on NASDAQ. We have in the past, and may in the future, be unable to comply with certain of the listing standards that we are required to meet to maintain the listing of ADSs on NASDAQ.

On January 25, 2024, we received a letter from the Listings Qualifications Department of The Nasdaq Stock Market LLC indicating that, based on the closing bid price of the ADSs for the last 30 consecutive business days, from December 11, 2023, to January 24, 2024, 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). In accordance with NASDAQ Listing Rule 5810(c)(3)(A), we have an initial period of 180 calendar days from the date of the notification letter from The Nasdaq Stock Market LLC, or until July 23, 2024, to regain compliance with the minimum bid price requirement. If at any time before July 23, 2024, the closing bid price of the ADSs is at least $1.00 for a minimum of ten consecutive business days, The Nasdaq Stock Market LLC will provide a written confirmation of compliance and the matter will be closed. In the event we do not regain compliance by July 23, 2024, we may then be eligible for an additional 180 calendar day period to regain compliance. To qualify, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for NASDAQ, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a change in the ratio between the ADSs and our ordinary shares, if necessary. However, if it appears to The Nasdaq Stock Market LLC staff that we will not be able to cure the deficiency during the second compliance period, or if we are not otherwise eligible, The Nasdaq Stock Market LLC will provide written notice that the ADSs are subject to delisting from NASDAQ. In that event, we may appeal the determination to a Nasdaq Stock Market LLC hearings panel. If we fail to regain compliance within our applicable cure period, or fail to satisfy other listing requirements, the ADSs may be subject to delisting.

We intend to monitor the closing bid price of the ADSs and may, if appropriate, consider implementing available options to cure the deficiency and regain compliance with the NASDAQ minimum bid price requirement within the compliance period. However, we can provide no assurance that any action taken by us would be successful, or that any such action would stabilize the market price or improve the liquidity of the ADSs.

If NASDAQ delists the ADSs from trading on its exchange for failure to meet the listing standards, an investor would likely find it significantly more difficult to dispose of or obtain ADSs, and our ability to raise future capital through the sale of ADSs could be severely limited. We additionally may not be able to list ADSs on another national securities exchange, which could result in our securities being quoted on an over-the-counter market. If this were to occur, our shareholders could face significant material adverse consequences, including limited availability of market quotations for ADSs and reduced liquidity for the trading of our securities. In addition, we could experience a decreased ability to issue additional securities and obtain additional financing in the future. There can be no assurance that an active trading market for ADSs will develop or be sustained. As a result of these factors, if the ADSs are delisted from NASDAQ, the price of our ADSs is likely to decline. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

If our ADSs are delisted from NASDAQ, we would remain a publicly traded company on the TASE and revert to being subject to full Israeli securities laws and disclosure requirements. Accordingly, we will need to comply with U.S. and Israeli disclosure requirements, and we expect that these additional reporting requirements would increase our 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 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 involving our ADSs, which could severely limit the market liquidity of the 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 NASDAQ 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.

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, if we become an "accelerated filer" or a "large accelerated filer" as those terms are defined under Rule 12b-2 of the Exchange Act, our independent registered public accounting firm will be required to attest to our evaluation of internal controls over financial reporting. Unless we successfully design and implement changes to our internal controls and management systems, or if we fail to maintain the adequacy of these controls as such standards are modified or amended from time to time, we may not be able to comply with Section 404. As a result, our auditors may be unable to attest to the effectiveness of our internal controls over financial reporting. This could subject us to regulatory scrutiny and result in a loss of public confidence in our management, which could, among other things, adversely affect the price of our ordinary shares and our ability to raise additional capital.

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, 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 are a non-accelerated filer, and we cannot be certain if the reduced disclosure requirements applicable to us will make our ADSs less attractive to investors.

We are currently a "non-accelerated filer", as those terms are defined in the Securities Act. Accordingly, we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not a "non-accelerated filers," in particular, reduced disclosure obligations regarding exemptions from the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002 requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting. Decreased disclosures in our SEC filings due to our status as a "non-accelerated filer" may make it harder for investors to analyze our results of operations and financial prospects.

We cannot predict if investors will find our ADSs less attractive if we rely on exemptions applicable to smaller reporting companies and non-accelerated filers. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and our ordinary share price may be more volatile.

We may be classified as a Passive Foreign Investment Company, or PFIC, for U.S. federal income tax purposes in 2023 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 2023 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. We have also agreed contractually under the Sales Agreement to provide an interim balance sheet and income statement as of the end of the first and third quarters 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, 2024. In the future, we would lose our foreign private issuer status if (1) more than 50% of our outstanding voting securities continue to be 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.

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

The 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 the 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' rights.

The effect of this discretionary proxy is that a holder of the 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 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 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 shares and ADSs.

Investors in the 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 the ADSs may not receive any value for them, if it is illegal or impractical to make them available to investors in the ADSs.

The depositary for the ADSs has agreed to pay investors in the 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 the 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 the 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 the 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 the 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 the 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 the 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 the 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 the 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.

The ADSs have relatively limited trading volume, which may limit the ability of our investors to sell their ADSs in the U.S.

The ADSs have been traded at low volumes in the past and may be traded at low volumes in the future for reasons related or unrelated to our performance. This low trading volume may result in lesser liquidity and lower than expected market prices for ADSs, and our investors may not be able to resell their ADSs for more than they paid for them.

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 and ADSs 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 and ADSs 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 ordinary shares or ADSs, the price of our ordinary shares and ADSs could decline.

The trading market for our ordinary shares and ADSs will rely in part on the research and reports that equity research analysts publish about us and our business. The price of our ordinary shares and ADSs could decline if such research or reports are not published or if one or more securities analysts downgrade the 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, including under our ATM program, to expand our clinical development program, expand our clinical development pipeline for additional drug products, including by way of possible acquisitions, expand our pre-clinical development activity 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.

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. 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 biopharmaceutical company, whose main asset is CM24, a clinical stage humanized monoclonal antibody in the oncology therapeutic field.

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

In December 2021, we decided to discontinue the manufacturing and distribution of Consensi.

In February 2023, we completed the acquisition of Immunorizon, a privately held biotech company developing multi-specific antibodies as oncology therapies that selectively activate the immune response within the TME. For information regarding the Immunorizon acquisition, see "Item 10 – Additional Information – C. Material Contracts – Immunorizon Acquisition."

For a description of our principal capital expenditures for the three years ended December 31, 2023, see "Item 5. *Operating and Financial Review and Prospects*."

B. Business Overview

We are a clinical-stage company developing first-in-class, effective and durable therapies that harness the power of the TME to overcome tumor immune evasion and drug resistance.

We are focused on oncology and our pipeline includes: (i) CM24, a humanized monoclonal antibody that blocks the interactions of Carcinoembryonic Antigen Related Cell Adhesion Molecule 1 (CEACAM1), an immune checkpoint protein that supports tumor immune evasion and survival through multiple pathways, (ii) NT219, a small molecule that simultaneously targets and inhibits Insulin Receptor Substrate 1 and 2 (IRS1/2) and Signal Transducer and Activator of Transcription (STAT3), two signal transduction pathways in oncology and the development of cancer drug resistance, as further described below and (iii) a platform technology of conditionally-activated tri-specific antibodies engaging both T cells and NK cells to induce a strong, localized immune response within the TME. A cleavable capping technology confines the compound's therapeutic activity to the local TME, which increases the anticipated therapeutic window in patients. The third arm of the antibody specifically targets the tumor-associated antigen (TAA). This technology presents a novel mechanism of action by unleashing both innate and adaptive immune systems at the TME to induce an optimal anti-tumor immune response. IM1240 is the platform's lead tribody in development that targets the 5T4 expressed in a variety of solid tumors and is correlated with advanced disease, increased invasiveness and poor clinical outcomes. In developing these therapeutic candidates, we address not only the tumor itself but also the TME, which we believe may improve patient outcome.

- We are conducting a randomized, controlled, open label, multicenter Phase 2 study to investigate CM24 in combination with the anti-PD-1 checkpoint inhibitor nivolumab for the treatment of pancreatic ductal adenocarcinoma (PDAC) when administered in combination with standard of care chemotherapy as a second line treatment, as compared to standard of care chemotherapy. We have entered into a clinical collaboration agreement with Bristol Myers Squibb to evaluate the combination of CM24 with Bristol Myers Squibb's PD-1 inhibitor nivolumab and nab-paclitaxel, in patients with pancreatic cancer, in this study. We completed patient enrollment in the study in December 2023, and expect to release interim results in the first half of 2024 and a topline report on the overall study by the end of 2024.

- We are concluding a phase 1 dose escalation study of NT219 as a single agent in patients with solid tumors and a dose escalation phase of NT219 in combination with cetuximab, for the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck cancer and colorectal adenocarcinoma. In February 2024, we determined the RP2D for NT219. We are currently planning the phase 2 study of NT219 at its RP2D level in combination with cetuximab for treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck in the first half of 2024.

- We are conducting preclinical studies with our tribody platform and expect to submit an IND application to the FDA for our first tribody, IM1240, in approximately two years.

In addition, we are seeking the acquisition of additional oncology therapeutic candidates at various stages of development to expand and diversify our portfolio and to leverage our development capabilities. We currently have no binding material agreements or commitments to complete any transaction for the possible acquisition of new therapeutic candidates or approved drug products.

Background on our therapeutic candidates

CM24 is a clinical stage humanized monoclonal antibody directed against CEACAM1, a multi-faceted membrane protein belonging to the Human CEA (Carcino-Embryonic Antigen) protein family that acts as an immune checkpoint inhibitor, a pro-angiogenic, anti-apoptotic agent and a promoter of tumor invasiveness and metastases. Evidence has shown that CEACAM1 is expressed on different white blood cells including lymphocytes neutrophils and monocytes and its expression is up-regulated in several cancer types. Additionally, previous publications in the scientific literature* indicate that CEACAM1 is expressed on neutrophil extracellular traps (NETs) which, among other activities, are believed to promote metastatic processes of tumors. Preclinical studies have shown evidence that CM24 enhances the cytotoxic activity of tumor-infiltrating lymphocytes (TILs) against various CEACAM1-positive tumor cell lines in vitro and in vivo. Our preclinical studies have shown that CM24 attenuates NET-induced tumor cell migration. 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 escalation study of CM24 as a single agent, a stable disease rate of approximately 33% among the evaluable patients was noted. In a second Phase 1 dose escalation study of CM24 in combination with the PD-1 inhibitor nivolumab, a disease control rate of 36% among the evaluable patients was noted, including one partial response and three stable diseases. We are developing CM24 as a combination therapy with the anti-PD-1 checkpoint inhibitor nivolumab and standard of care chemotherapy in a Phase 2 study in patients with pancreatic cancer as a second line treatment. We entered into a clinical collaboration agreement with Bristol Myers Squibb for this study. For more information regarding CM24, see, "Item 4. Information on the Company – B. Business Overview - Our Therapeutic Candidates – CM24".

* Rayes RF, et al. Neutrophil Extracellular Trap-Associated CEACAM1 as a Putative Therapeutic Target to Prevent Metastatic Progression of Colon Carcinoma. J Immunol. 2020 Apr 15;204(8):2285-2294. PMID: 32169849; and

* Masucci MT, Et. al. The Emerging Role of Neutrophil Extracellular Traps (NETs) in Tumor Progression and Metastasis. Front Immunol. 2020 Sep 16;11:1749. PMID: 33042107.

NT219 is a novel small molecule that targets IRS1/2 to degradation, and demonstrates the ability of inhibiting both IRS1/2 and STAT3, two key oncology-related proteins, which play major roles in cancer cell survival, drug resistance, angiogenesis, metastasis and immune evasion. NT219 demonstrated efficacy in multiple xenograft and patient-derived xenograft (PDX) preclinical models as a monotherapy but mainly in combination with various classes of cancer drugs such as targeted therapies (against EGFR, mitogen-activated protein kinase (MEK), mutated BRAF) and chemotherapies, overcoming drug resistance and suppressing refractory tumors to these approved therapies. Suppression of refractory tumors to immune check inhibitors by the combination of NT219 with anti-PD1 therapy was presented as well, accompanied by reprogramming of the immune profile and conversion of immunosuppressive TME to immunoreactive. We conducted a phase 1/2 dose escalation study of NT219 as a single agent in patients with solid tumors and a dose escalation phase of NT219 in combination with cetuximab, for the treatment of recurrent and/or metastatic squamous cell carcinoma of the head and neck and colorectal adenocarcinoma. In February 2024, we determined the RP2D for NT219. The Phase 1 dose escalation study is being concluded and the remaining patients' data are expected to be reported during the first half of 2024. We are currently planning a phase 2 study of NT219 at its RP2D level in combination with cetuximab for treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck, which we plan to commence during the first half of 2024. For more information regarding NT219, see "Item 4. Information on the Company – B. Business Overview - Our Therapeutic Candidates – NT219."

Tribody platform technology of conditionally-activated tri-specific antibodies engaging both T cells and NK cells to induce a strong, localized immune response within the TME is in pre-clinical development. A cleavable capping technology confines the compound's therapeutic activity to the local TME, which increases the anticipated therapeutic window in patients. The third arm of the antibody specifically targets the TAA. This technology presents a novel mechanism of action by unleashing both innate and adaptive immune systems at the TME to induce an optimal anti-tumor immune response. IM1240 is the platform's lead tribody in development that targets the 5T4 expressed in a variety of solid tumors and is correlated with advanced disease, increased invasiveness and poor clinical outcomes. Our portfolio includes additional early-stage assets, targeting other receptors and TAA. For more information regarding tribody platform, see "Item 4. Information on the Company – B. Business Overview – Our Therapeutic Candidates – Tribody Platform Technology."

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, 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.

We believe there are several advantages to the therapeutic candidates we are developing, as set forth below.

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 (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 T-cells, NK cells, monocytes and neutrophils.

- CEACAM1 has been proposed to be 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 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 manifested through its expression on neutrophil extracellular traps (Rayes RF, et al. J Immunology. 2020) and our data.

Finally, CM24 has been evaluated as monotherapy at escalating doses up to 10mg/kg in a phase 1 clinical trial, where 27 patients with different cancers in advanced stages were treated with the monoclonal antibody. There were no dose limiting toxicities which were associated with CM24, nor any drug related mortalities. In a second Phase 1b study, CM24 at 3 dose levels, 10, 15 and 20mg/kg, was administered in combination with standard dose of nivolumab to a total of 14 patients with PDAC, CRC and papillary thyroid cancer. The combination of CM24 and nivolumab was well tolerated and demonstrated initial signals of efficacy. A randomized, controlled, open label, multicenter Phase 2 study evaluating CM24 in combination with nivolumab and standard of care chemotherapy in patients with pancreatic ductal adenocarcinoma as a second line treatment as compared to standard of care chemotherapy was initiated and enrollment was completed during December 2023.

NT219:

NT219 is a first in class and currently the only drug candidate to the best of our knowledge that inhibits both IRS1/2 and STAT3, where inhibition of both was demonstrated essential to facilitate significant anti-tumor effect and overcome drug resistance.

NT219 binds covalently to IRS1 and IRS2 and targets them to degradation, gaining a sustained inhibition of IRS1/2-mediated signaling. Prolonged inhibition of STAT3 was also demonstrated, long after the drug was washed out.

NT219 is a small molecule, and small molecules are typically less expensive to develop and have less complex CMC as compared to proteins or antibodies.

In preclinical development, NT219 demonstrated several advantageous effects in animal models, such as:

- single agent activity in PDX and xenograft models;
- overcoming drug resistance acquired by various cancer types;
- synergistic anti-tumor effects in combination with approved cancer therapies belonging to various classes such as chemotherapy and targeted therapies; and
- suppression of refractory tumors to immune check inhibitors by the combination of NT219 with anti-PD1 therapy. The effect on tumor growth was accompanied by the conversion of immunosuppressive TME to immunoreactive (upregulation of cytotoxic T cells and NK cells paralleled with a decrease in T regulatory cells, tumor-associated macrophages and MDSCs).

In the monotherapy portion of the phase 1/2 dose escalation study of NT219, no dose limiting toxicities (DLTs) have been observed and NT219 has been found to be well tolerated with no treatment-related Grade 4/5 AEs.

In the dose escalation study of NT219 in combination with cetuximab, anti-tumor activity was observed in previously treated HPV negative 2L/3L R/M SCCHN patients. As of January 25, 2024, 17 patients were enrolled in the combination arm; 15 patients were evaluable for efficacy, 7 of which were at the highest dose levels of 50+100 mg/kg. Out of these 7 patients, 2 patients demonstrated confirmed partial response and 3 patients demonstrated stable disease, representing a 29% objective response rate (ORR) and 71% disease control rate (DCR). Median follow-up across all dose levels is 9.4 months (95% CI: 3.4-10.0, 8 out of 15 patients remaining in follow up). Safety profile was well tolerated and manageable up to and including at 100mg/kg. Most common treatment emergent adverse events (AEs) were infusion related reactions and nausea and no treatment-related Grade 4/5 AEs were observed. Pharmacokinetic analysis demonstrated dose dependent increase. We determined the RP2D for NT219 at 100mg/kg. The Phase 1 dose escalation study is being concluded and we plan to commence a Phase 2 study in combination with cetuximab in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck cancer in the first half of 2024.

Tribody Platform Technology and IM1240:

Our tribody platform technology of conditionally-activated tri-specific antibodies is a multi-valent antibody designed to activate anti-tumoral immune response against TAA positive tumors.

The two features described below represent advantages of our tribody platform as they provide specific anti-tumor effects at the tumor site with reduced side effects, as well as efficient activation of the anti-tumoral immune response.

- Dual activation of T cells and NK cells to induce a stronger specific immune response against cancer cells (Kyrysyuk et al., Annu. Rev. Immunol. 2023. 41:17–38); and
- A cleavable capping system aimed to prevent systemic T cell engagement, improve safety profile and pharmacokinetic properties, and widen the therapeutic index.

The tribody platform is a wide platform that allows incorporation of antibodies against various TAAs, and thereby produces a pipeline of products that target multiple cancer types expressing these TAAs. It is also versatile in terms of the NK cell targets.

The IM1240 therapeutic candidate has distinctive features that we believe could allow it to outperform competitors. 5T4 is a well-studied TAA, minimally expressed in healthy tissues and associated with poor prognosis in multiple cancer types.

Our strategy

Our goal is to become a leading 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, representing 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 therapeutic candidates in pre-clinical and 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;
- develop new disruptive and innovative technologies in collaboration with third parties, as well as using our in-house capabilities; and
- cooperate with third parties, to both develop and commercialize therapeutic candidates in order to share costs and leverage the expertise of others.

Our oncology therapeutic candidates, CM24, NT219 and the tribody platform with its leading therapeutic candidate IM1240, are further described below.

CM24

Background

CM24 is a humanized monoclonal antibody directed against CEACAM1, a multi-faceted membrane protein belonging to the Human CEA (Carcino-Embryonic Antigen) protein family that acts as an immune checkpoint inhibitor, a pro-angiogenic, anti apoptotic agent, and a protein that promotes tumor invasiveness and metastases. Evidence has shown that CEACAM1 is expressed on tumor infiltrating lymphocytes and its expression 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 Dr. Gal Markel from Sheba Medical Center and initially developed by cCAM Biotherapeutics Ltd. (cCAM), which was acquired by Merck Sharp and Dohme Corp., or 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. Despite no known safety risks, MSD discontinued the clinical study and 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.

The Therapeutic Candidate

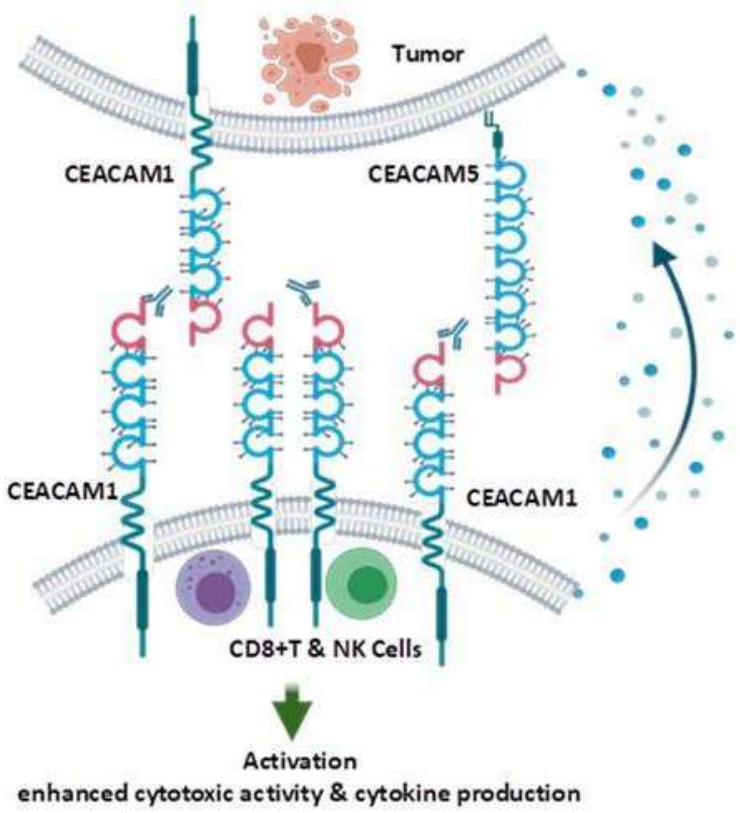
CM24 is a humanized monoclonal antibody directed against CEACAM1, a multi-faceted membrane protein belonging to the Human CEA (Carcino-Embryonic Antigen) protein family that acts as an immune checkpoint inhibitor, a pro-angiogenic, anti apoptotic agent, and a protein that promotes tumor invasiveness and metastases.

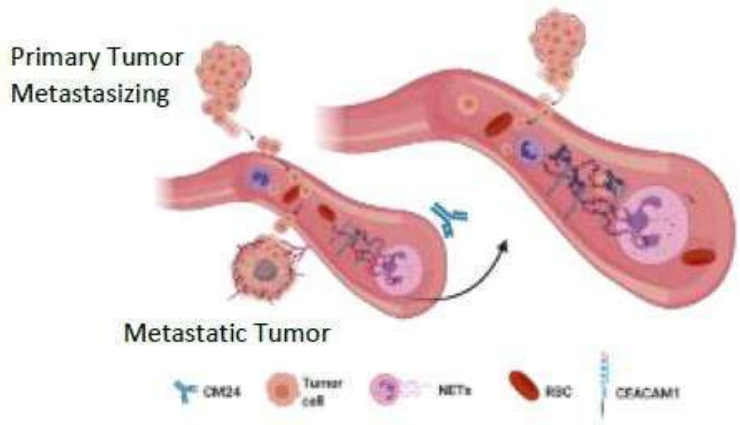
CEACAM1 belongs to the CEA superfamily. CEACAM1 interacts with itself (i.e., hemophilic interaction) and with CEACAM5 (heterophilic interaction), as well as with various bacterial proteins. Different functions have been attributed to the CEACAM1 protein: anti-proliferative properties in carcinomas of the colon and prostate, or facilitation of proliferation in melanoma; central involvement in angiogenesis, insulin clearance and 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 cancer tissues and 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, attenuating metastatic processes, preventing angiogenesis, and promoting tumor apoptosis.

CEACAM1 is part of the neutrophil extracellular trap (NET) complex. NETs are regarded as an important member of the TME, which contribute to metastatic dissemination and immune evasion. We have demonstrated direct binding of CM24 to NETs, and inhibition of NET-induced cancer cell migration by CM24. The effects on NETs demonstrate a novel mechanism of action for CM24, which may support the role of CM24 in controlling immune evasion, metastasis, NET-related complications and patient's survival.





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 Dr. Gal Markel from the Tel HaShomer Medical Center**. In September 2023, we reported initial results of potential biomarkers for CM24 therapy, that were presented in a poster entitled "Phase 1 Study of CM24 in Combination with Nivolumab in Patients with Advanced Pancreatic Cancer – Survival, Exploratory Biomarkers and Effect on Neutrophil Extracellular Traps (NETs)" at the American Association of Cancer Research (AACR) Special Conference: Pancreatic Cancer. Exploring the patient's biopsies and serum samples of the first part of our CM24 Phase 1/2 clinical study to search for potential biomarkers, we showed that higher levels of CEACAM1-positive tumor infiltrating lymphocytes pre treatment may associate with longer survival in patients treated with CM24 and nivolumab. In addition, we demonstrated for the first time that CM24 treatment significantly reduced the level of NET marker MPO in patients' serum.

* 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 as a dose escalation stage that was to be followed by an expansion stage. The trial was concluded following administration of CM24 to 27 patients and prior to determining the recommended phase 2 level and 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 liver function tests (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 24 evaluable patients was achieved, mostly in the two highest dose groups, where approximately 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 and chemotherapy 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. As noted, the doses used in the aforementioned study were below those required to reach target saturation as determined by pharmacokinetic evaluations.

A Phase 1/2 study that includes three parts is ongoing. The first part which has already been completed included a dose escalation of CM24 at 10, 15 and 20mg/kg, in combination with standard dose of the PD-1 inhibitor nivolumab, in patients with selected solid tumors who have received up to 2 prior regimens for their advanced and/or metastatic disease. The primary objective of this part of the study was to evaluate safety, tolerability, PK and determine the RP2D.

In June 2021, we reported on the first dose cohort of the dose escalation phase (10mg/kg), where one patient with refractory advanced MSI-S pancreatic cancer having been previously treated with two previous regimens, had a confirmed partial response to CM24 and nivolumab, both with respect to imaging and biochemical markers. The responsive patient showed a 40% reduction in tumor size following two cycles of treatment with CM24 in combination with nivolumab 480mg/kg. In addition, levels of CA19-9 tumor marker dropped by 56%, compared to baseline levels. Additionally, there were no dose-limiting toxicities or serious adverse events observed in any of the three patients enrolled in the first dose cohort of the study.

In July 2023, we reported clinical data from the first part of the Phase 1/2 study. Fourteen patients were evaluable for efficacy, out of which 11 were PDAC patients. Best overall response included 1 Partial Response (PR) (PDAC) and 4 Stable Disease (SD) (3 PDAC and 1 papillary thyroid cancer (PTC)). No DLTs were observed across all dose levels; no Grade 4 or higher adverse events (AEs) or treatment related deaths have been reported. Pharmacokinetic analysis of CM24 shows exposure is dose-proportional across the 3 doses in this study. Median Overall Survival 4.5 months (95% CI 2.0-11.1) for 11 PDAC patients.

The second part of the study, which has been completed, was designed as a safety (primary endpoint) run-in stage, enrolled patients with advanced/metastatic PDAC who have received up to one prior regimen for their disease. In this part of the study, PDAC patients received CM24 at 20mg/kg plus nivolumab at 240mg and one of the following two standard of care chemotherapy regimens of either gemcitabine and nab-paclitaxel or liposomal-irinotecan (Nal-IRI), 5-fluorouracil and leucovorin. A total of 16 PDAC patients were enrolled in this part of the trial. No DLTs were noted in those patients.

In February 2023, we reported enrolment of the first patient to the third part of the study. This part of the study is a randomized, controlled, opened labeled, multi-center study, comparing treatment of PDAC patients who have received up to one treatment regimen for their advanced/metastatic disease with CM24, nivolumab and standard of care (SoC) chemotherapy (experimental cohort) vs. SoC chemotherapy (control cohort). This randomized Phase 2 study is designed to include approximately 30 patients in the experimental cohort and approximately additional 30 patients in the control cohort. In December 2023, we reported enrollment completion for this part of the study. The study is currently being conducted in 18 sites in the United States, Spain and Israel. The primary endpoint of this randomized part of the trial is overall survival while additional efficacy (e.g., PFS, OS rate at 6 and 12 months, PFS rates at 3 and 6 months, ORR and DOR) and safety measures will be part of the secondary endpoint of the trial. The study will also include different assessments of tumor tissue and blood aimed at exploring potential biomarkers. The trial is conducted in clinical collaboration with Bristol Myers Squibb. Additional information about the trial can be found at www.clinicaltrials.gov, NCT Identifier NCT04731467.

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 IRS 2 and STAT3 pathways. 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., head and neck, pancreatic, 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.

Tumor Resistance to Immunotherapy. While the advent of immune checkpoint blockade (ICB) has dramatically improved the prognosis of many immune-infiltrated cancers, for others, unfortunately, these benefits have yet to be realized. The main challenge in this field is to identify combination therapies that can convert immunosuppressive TME to immunoreactive and combat evolved resistance.

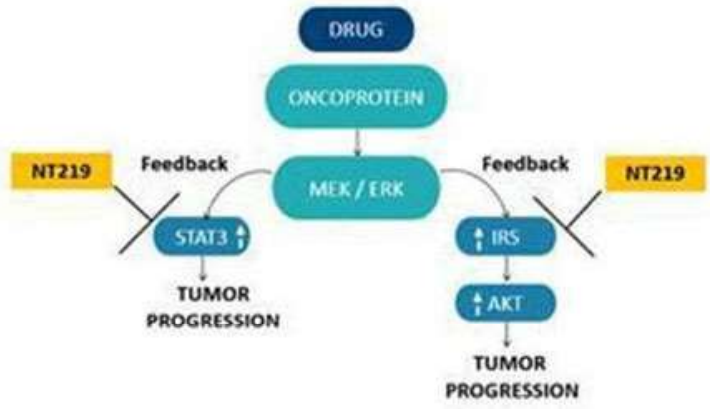
IRS. Insulin Receptor Substrate (IRS) is a junction protein that mediates various mitogenic and anti-apoptotic signals mainly from Insulin-like Growth Factor-1 Receptor (IGF1R) and Insulin Receptor (IR), but also from other oncogenes such as v-Src and ALK-fusion proteins. IRS expression is often up-regulated 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 irinotecan).

Mechanism of Action

The NT219 is a first in class small molecule and the only therapeutic candidate to the best of our knowledge that acts as a dual inhibitor of IRS1/2 and STAT3, both of which play major roles in oncogenesis and cancer drug resistance. While most targeted anti-cancer drugs inhibit the "ON" signal, NT219 activates the "OFF" switch, leading to serine phosphorylation and degradation of IRS-1/2, reducing STAT3 phosphorylation, 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, BRAF) 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 IRS 1/2 and with low nano-molar affinity to the 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.

In April 2021, we reported additional preclinical data supporting the mechanism of action of NT219, that was presented in a poster entitled "Adaptation of colorectal cancer cells to the brain microenvironment: The role of IRS2," at the American Association of Cancer Research (AACR) 2021 Annual Meeting. Colorectal cancer (CRC) represents the fourth most frequent cause of brain metastasis, which is the most common brain tumor. The preclinical data updates and expands on the results previously reported by the Company in collaboration with Dr. Ido Wolf, Head of the Oncology Division at Tel Aviv Sourasky Medical Center. The study included an analysis of more than 16,000 human CRC local and metastasis samples and revealed an increased amplification of IRS2 in brain metastases. In an in vitro system mimicking the brain microenvironment, IRS2-overexpressed CRC cells showed prolonged survival. Importantly, transcriptomic analysis demonstrated significant enrichment of the oxidative phosphorylation (OXPHOS) pathway by IRS2. CRC cells expressing IRS2 showed increased mitochondrial activity and glycolysis-independent viability. Inhibition of IRS2 using NT219 dose- dependently inhibited IRS2-expressing cells viability and OXPHOS genes expression. The Wnt/β-catenin pathway was among the most significantly enriched pathways in the brain metastasis, as IRS2-expressing cells showed increased transcriptional activity of the β-catenin. In addition, NT219 decreased the transcriptional activity of β-catenin in IRS2- expressing CRC cells to a greater extent than AKT and PI3K inhibitors, and most significantly suggested relevance of IRS2 in activating β- catenin. It was further shown that 5-FU, a chemotherapy approved for treating CRC, elevated β-catenin expression, and that NT219 diminished both 5FU-induced and the basal level of the β-catenin expression. Utilizing an intracranial animal model, it was also demonstrated that while 5-FU alone had no significant effect, the combination of 5-FU and NT219 significantly inhibited the formation of brain metastasis and extended survival rates of the study mice.

In October 2021, an article was published in Nature Cancer demonstrating mechanisms behind cancer cell persistence frequency and potential of NT219 to reduce therapeutic resistance. The article titled, "IRS1 phosphorylation underlies the non-stochastic probability of cancer cells to persist during EGFR inhibition therapy". The lead author of the publication is Ravid Straussman, M.D., Ph.D., Department of Molecular Cell Biology, Weizmann Institute of Science, Rehovot, Israel. The article demonstrated mechanistic evidence of cancer cells' inherited therapeutic resistance, termed chance to persist (CTP). It was shown in preclinical models, that the CTP EGFR inhibition is modulated by serine/threonine phosphorylation of the IRS1. Specifically, it has been shown that higher phosphorylation of IRS1 multiple serine/threonine sites, which blocks IRS1 activity, results in increased susceptibility to EGFR inhibitors. A combination of NT219, which triggers serine phosphorylation and subsequent degradation of IRS1 and EGFR inhibitors, resulted in a synergistic effect, leading to tumor regression and delayed recurrence upon treatment withdrawal.

Preclinical results

In preclinical 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 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 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.

In 2021, we expanded an existing research agreement, led by Menashe Bar-Eli, Ph.D., Professor, Department of Cancer Biology, at The University of Texas MD Anderson Cancer Center, to evaluate the potential efficacy of the combination of NT219 and immuno-oncology drugs, such as anti-CTLA4 or anti-PD1/PDL1 antibodies.

In April 2023, we reported preclinical results of this research and supportive mechanism of action data, that was presented in a poster entitled "NT219 induces tumor PD-L1 expression and potentiates anti-PD-1 efficacy" at the American Association of Cancer Research (AACR) 2023 Annual Meeting. The findings showed that NT219 sensitizes resistant melanoma tumors to αPD-1 and prolongs mouse survival, providing a rationale for combining anti-PD-1 therapy with NT219 as a potential strategy to overcome resistance to immune checkpoint blockade (ICB) therapy.

Immune profiling of the ICB-resistant tumors following treatment of the mice with the combination of NT219 with α-PD-1 or α-CTLA4 demonstrates reprograming of the TME and reveals enhanced infiltration and activation of cytotoxic T cells and NK cells, paralleled with a decrease in T regulatory cells, M2 macrophages and monocytic and granulocytic myeloid-derived suppressor cells (MDSCs), suggesting the potential of this combinations to restore the efficacy of anti-PD-1 and anti-CTLA4 therapies by converting immunosuppressive TME to immunoreactive.

Clinical Development

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 first in human studies 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 is 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 first in human Phase 1 study of NT219, which we commenced in the second half of 2020, evaluated single agent NT219 at a dose escalation, in patients with advanced cancer diseases. Patients for this component of the trial (deemed Part A) were evaluated for safety as the primary endpoint, and efficacy as a secondary endpoint. The escalation took the form of a 3+3 standard design, together with a "backfill" groups enrolling of up to 3 additional patients at doses which had already been deemed safe. Patients were administered NT219 weekly until disease progression or study withdrawal for any other cause**.**

In December 2021, we initiated Part B of our ongoing Phase 1/2 clinical trial of NT219, as a dose escalation study of NT219, beginning with 6mg/kg, in combination with the standard dose of cetuximab (ERBITUX®), in patients with recurrent and/or metastatic squamous cell carcinoma of head and neck cancer (SCCHN) and colorectal adenocarcinoma (CRC). In this arm, patients with advanced cancer, who were eligible for cetuximab therapy (e.g., SCCHN and CRC), received a combination of the drugs, with NT219 being administered first, followed by cetuximab, in a similar course of weekly administrations. The combination was evaluated in a similar 3+3 design and backfill groups as described for single agent part of the study.

These two parts of the study provided information regarding the safety of NT219 as a single agent and in combination with cetuximab, including the determination of the recommended phase 2 dose (RP2D), as well as preliminary efficacy signal of NT219 as a single agent and in combination with cetuximab.

In February 2024, we reported that the recommended Phase 2 dose for NT219 in combination with cetuximab for the treatment of R/M SCCHN patients based on the Phase 1/2 dose escalation study was determined to be 100mg/kg.

In February 2024, we also reported clinical data from the Phase 1 dose escalation study of NT219 in combination with cetuximab in the treatment of patients with recurrent and/or metastatic head and neck cancer. In the dose escalation study of NT219 in combination with cetuximab, anti-tumor activity was observed in previously treated HPV negative 2L/3L R/M SCCHN patients. As of January 25, 2024, 17 patients were enrolled in the combination arm; 15 patients were evaluable for efficacy, 7 of which were at the highest dose levels of 50+100 mg/kg. Out of these 7 patients, 2 patients demonstrated confirmed partial response and 3 patients demonstrated stable disease, representing a 29% objective response rate (ORR) and 71% disease control rate (DCR). Median follow-up across all dose levels is 9.4 months (95% CI: 3.4-10.0, 8 out of 15 patients remaining in follow up). Safety profile was well tolerated and manageable including at the recommended dose level of 100mg/kg. Most common treatment emergent AEs were infusion related reactions and nausea and no treatment-related Grade 4/5 AEs were observed. Pharmacokinetic analysis demonstrated dose dependent increase. The Phase 1 dose escalation study is being concluded and we plan to commence a Phase 2 study of NT219 at its RP2D level in combination with cetuximab for treatment of patients with recurrent and/or metastatic head and neck cancer in the first half of 2024.

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

We are not familiar with other therapeutic candidates acting as dual inhibitor of both IRS1/2 and STAT3. Similarly, we are not aware of any other inhibitor of IRS1/2 in active development. However, there are some clinical-stage STAT3 inhibitors, such as danvatirsen, an antisense nucleotide developed by AstraZeneca for pancreatic, NSCLC and mismatch repair deficient colorectal cancers. Although they are not direct competitors of NT219, inhibitors of Insulin Like Growth Factor 1 Receptor (IGF1R) acting upstream of IRS1/2, such as dalotuzumab, developed by Merck & Co for pancreatic cancer, or ganitumab, developed by Amgen in Ewing Sarcoma, are also closely monitored.

Tribody Platform Technology

Background

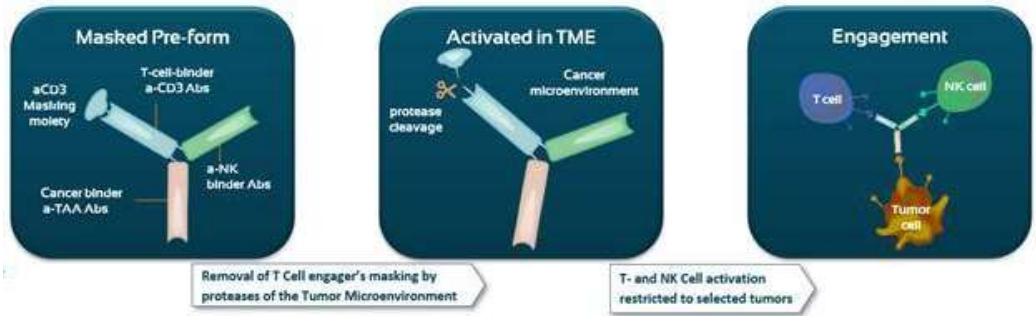
For decades, cancer research has been heavily focused on therapeutic modalities directly targeting cancer cells such as radio- or chemotherapy. Despite providing significant improvement of patient outcome, these treatments have significant limitations related to poor tolerability and acquired resistance mechanisms. More recently, further to a better understanding of tumor escape mechanisms, the rise of immuno-oncology approaches opened new horizons. Immune checkpoint inhibitors designed to release effector immune cells from inhibitory signals delivered by cancer cells and the TME have become the backbone therapy in numerous oncology indications and new strategies have been explored to redirect immune cells towards malignant cancer cells.

T cell engagers is an emerging therapeutic modality that consists in linking tumor infiltrating T cells to target tumor cells via antibody-derived products. By binding to a tumor associated antigen (TAA) with one arm and to the CD3 molecule associated with the T cell receptor (TCR) with the other arm, T cell engagers promote the formation of a cytolytic synapse between T cells and cancer cells leading to destruction of the tumor. Conceptually, any cytotoxic immune effector cell can be engaged by this modality including CD8+ T cells, gamma-delta T cells, NK and NKT cells. In this context, T-cell engagement is independent of the specific recognition of a peptide-MHC complex and in principle, every tumor infiltrating T cell with cytotoxic potential is expected to be activated by T cell engagers. The first success with this new approach came from blinatumomab, a CD19/CD3 bispecific that achieved 40% complete response in patients with acute lymphocytic leukemia (ALL) leading to accelerated approval by the FDA in 2018. Based on our knowledge, multiple T cell engagers are currently being explored in advanced clinical trials.

The increase in T cell engagers or more generally immuno-engagers that are in development is directly related to the progress in protein engineering technologies allowing to derive new antibody-based compounds with distinctive features. Compared to monospecific monoclonal antibodies, multi-specific constructs potentiate antibody-mediated effects, for example they can be used to “crosslink” immune cells and cancer cells expressing specific TAAs, they can bind two epitopes on the same target to avoid resistance or they can interact with several TAAs or several immune cells. Numerous formats of bispecific antibody-based therapeutic candidates are being investigated in clinical studies and the possibilities are further increasing with the emergence of tri- and multi-specific compounds some of which have already shown potential promising data and are entering clinical testing. The main field for all of these compounds is oncology, and in general, at least one of the specificities is intended to redirect T- or NK cells. Based on new research and clinical insights, the rationale for dual engagement of T and NK cells is attaining stronger recognition and this is one of the main features of our tribody platform.

Tribody Platform Description

Our tribody platform technology is comprised of conditionally-activated tri-specific antibodies engaging both T cells and NK cells to induce a strong, localized immune response within the TME. A cleavable capping technology confines the compound’s therapeutic activity to the local TME, which increases the anticipated therapeutic window in patients. The third arm of the antibody specifically targets the TAA. This technology presents a novel mechanism of action by unleashing both innate and adaptive immune systems at the TME to induce an optimal anti-tumor immune response.



T cell engagement is achieved through binding CD3 using a commercially validated antibody fragment. CD3 is a protein complex associated to the T cell receptor on the surface of both $CD4^+$ and $CD8^+$ T cells. Agonistic binding to CD3ε triggers T cell activation that is mediated by Lck/Zap70 and leads to downstream activation of multiple signaling pathways such as NK-kB or NF-AT. Anti-CD3 is the backbone of the vast majority of bispecific T cell engagers. Three were already approved by the US FDA (Blinatumomab, CD3×CD19 in 2014 for acute lymphoblastic leukemia, Tebentafusp, CD3×IMCgp100 in 2022 for Uveal Melanoma, teclistamab, CD3xBCMA in 2022 for Multiple Myeloma) and a large number other BiTE are currently in clinical development.

The NK cell mediated activity is manifested by the NK cell engager arms of NKG2A or NKG2D. The NKG2A arm of the tribody blocks the interaction between NKG2A, an inhibitory receptor expressed on NK cells or CD8+ T-cells, and the HLA-E ligand expressed on cancer cells. Blockage of the inhibitory effect of NKG2A-HLA-E interaction allows NK and T-cell activation and thereby, promotes tumor suppression, and consequently induces cell killing. The NKG2D of the tribody arm inhibits the interaction between NKG2D, an activating receptor expressed on NK cells and CD8+ T-cells, and its ligands expressed on cancer cells, eliciting cytotoxicity of NK and T cells against the tumor. This activation of NKG2D triggers cellular proliferation, cytokine production, and cancer cell killing.

In addition to its unique combination of the TAA, CD3 and NK cells binding arms, our tribody platform is also differentiated from competing products with a cleavable cap, which limits the compound's therapeutic activity to the local TME. This cap is attached to the anti-CD3 moiety and blocks its interaction with circulating CD3 positive T cells thereby impeding potential off-tumor adverse reactions. The cap is designed to be cleaved-off by multiple TME-specific proteases, which increase the likelihood for cleavage by many tumor types. Upon removal of this cap, the anti-CD3 moiety of the molecule is freed to bind and activate T lymphocytes via CD3.

Our lead tribody in development is IM1240 that targets 5T4 as TAA, which is expressed in a variety of solid tumors and is correlated with advanced disease, increased invasiveness and poor clinical outcome. IM1240 is directed towards 5T4 (also known as trophoblast glycoprotein (TPBG)), using a proprietary set of complementarity-determining regions (CDRs). 5T4 is an oncofetal surface protein that is not found on adult healthy tissues but is abnormally expressed in several cancer types. This specific expression pattern as well as the correlation with poor prognosis in different cancer diseases such as lung, gastric, head and neck and other cancers makes it an ideal TAA for various therapeutic approaches.

Preclinical data

IM1240 is the outcome of significant lead optimization work to maximize the compounds properties in terms of affinity, efficacy and safety. The different tribodies demonstrated high affinity for 5T4, CD3 and NK cell inhibitory receptor and efficient anti-tumor responses in in vitro killing assays.

The benefit of the dual T cell/ NK cell activation was demonstrated in cytotoxicity assays against various $5T4^+$ cancer cells lines, and in an autologous patient-derived NSCLC explant study, where the 5T4xCD3xNK tribody was more potent than either the 5T4xCD3 or the 5T4xNK variants. In terms of specificity no cytotoxicity was observed in 5T4 negative cancer cells.

The relevance and robustness of the cleavable capping system was investigated in xenograft models using immune-competent mice. Sustained tumor regression was achieved with the tribody harboring a cleavable cap. The effect was superior to a variant with no cap, illustrating the detrimental effect of peripheral engagement of tumor-irrelevant T cells. The efficacy was completely lost using a variant with non-cleavable cap in which the CD3 arm of the tribody remained blocked.

Additional preclinical investigations are ongoing to complete the functional characterization of the compound and, in parallel, CMC activities have been initiated to produce the first GMP-batch required to conduct IND-enabling studies.

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".

CM24

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

- *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. Two United States patents as well as two European counterparts were granted. The European patents are validated in Germany, France, Spain, Italy, United Kingdom, Ireland, The Netherlands, Poland and Switzerland. Patents were also granted in Brazil, Canada, China, 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 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, Brazil, Canada, China, India, Japan, Korea, 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. A divisional Patent application is allowed in Europe.

- *Patent Family 5* relates to humanized antibodies, including CM24, 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 (2 patents), Europe, Canada, China, Eurasia (validated in Russia) Israel, Japan Korea 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. A continuation-in-part application is pending in the United States, a divisional application is pending in Mexico and national phase applications are pending in Brazil (allowed), and India.

- *Patent Family 6* relates to use of CM24 in inhibition of NET-mediated activities and in prevention and treatment of pathologies associated with these activities. An international (PCT) application was filed on November 9, 2023 claiming priority from U.S. provisional applications filed on November 10, 2022 and September 21, 2023.

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.

Pursuant to 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.

NT219

TyrNovo's patent and patent application portfolio, covering NT219 and other compounds, includes six 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 IRS and STAT3, with various targeted drug classes (inhibitors of EGFR, mTOR; 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, Europe and Israel, 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 (allowed), Canada, China, Europe, 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 PD-1 protein and/or anti-programmed cell death protein 1 ligand (PD-L1). Patents were granted in Japan and Russia and have a maximum term of November 16, 2037. Patent applications are pending in Brazil, Canada, China, Europe, Israel, Korea, Mexico, and the United States.

- Patent Family 6 relates to the method which prevents the conversion of NT219 from its active form to a less active form and supports maintenance of the active form during manufacturing, storage and handling until administered to the patient. A Chinese patent was granted and has a maximum term of February 17, 2042. An international PCT patent application is pending. Any patent issued based on the PCT application will have a maximum patent term of October 3, 2042.

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. According to the settlement agreement with BIRAD and an amendment to the Yissum license agreement, BIRAD is entitled to receive a portion of Yissum's royalties on net sales.

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.

Tribody

- Patent Family 1 relates to conditionally activated tri-specific antibodies that engage T cells, NK cells, and tumor cells, including the antibody clone identified as IM1240, compositions thereof, and methods of use thereof for treating cancer in a subject in need. The tri-specific antibodies further include a cleavable capping technology for regulating the binding/activation of T cells to within a TME and for extending the half-life of the antibodies. National Phase applications have been entered and are pending in Australia, Brazil, Canada, China, Europe, Israel, India, Japan, the Republic of Korea, Mexico, and the United States. The expected term of any granted national phase application is May 4, 2041, not including patent term extension.

- In addition, we own four additional patent families related to conditionally activated tri-specific antibodies that engage T cells, NK cells and tumor cells including different TAAs with their respective CDRs and compositions thereof, and methods of use thereof for treating cancer as well as GvHD, viral or bacterial infections in a subject in need.

Other

We own three patent families covering uses of a monoclonal antibody, which we are currently evaluating for their potential for further development, for the purpose of treating cancer and infectious diseases, based on these patents.

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 CROs 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 preclinical 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 medical 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 a 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 to 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)(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 show 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 therapeutic candidates 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. Our 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 as follows:

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

Second, pertaining to research and development, when we conduct trials in humans 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), as amended, 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 principal investigator in the trial, submits an application that includes, among other documents, the investigator brochure, clinical trial protocol and the informed consent form, on behalf of the requesting party. This committee may request changes and/or additional documents. Applications which are approved by the Helsinki Committee are forwarded to the "high committee" at the IMOH, which reviews all documents. The IMOH may request additional changes or documents (Investigational Medicinal Product Document, or, for short IMPD, which includes details regarding the manufacturing testing and quality of the drug to be tested) as part of its approval process. The IMOH sends its decision, along with that of the IMOH, to the manager of the medical institute for approval. According to the procedure for medical trials in human beings of the IMOH, 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 Principal Investigator 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 sub-investigator(s) 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 IMOH and local SOPs; and (h) the nature of the commercial agreement with the Principal Investigator and the medical institute does not impair the adequate performance of the medical trial. The IMOH also licenses and regulates the marketing of pharmaceuticals in Israel, requiring the relevant pharmaceutical to meet internationally recognized cGMP standards.

Manufacturing of NT219 is conducted by service providers operating in Denmark and Italy and, as such, these service providers are periodically audited by the local medicine agencies, 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 for public health protection, 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 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 payments and other transfers of value to physicians (as defined by such law), certain other healthcare providers, and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members 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 oncology 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 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 therapeutic candidates, if approved, if they are covered by a Part D prescription drug plan. However, any negotiated prices for 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

On March 23, 2010, President Obama signed the "Patient Protection and Affordable Care Act" (P.L. 111-148) (the "ACA") and on March 30, 2010, he signed the "Health Care and Education Reconciliation Act" (P.L. 111-152), collectively commonly referred to as the "Healthcare Reform Law." The Healthcare Reform Law included a number of new rules regarding health insurance, the provision of healthcare, conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients, and other healthcare policy reforms. Through the law-making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the U.S., including changes made to extend medical benefits to certain Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and drugs, and imposing additional taxes, fees, and rebate obligations on pharmaceutical and medical device companies). This legislation was one of the most comprehensive and significant reforms ever experienced by the U.S. in the healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law's provisions were designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. This environment 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 surrounding pharmaceuticals. This attention may result in our current commercial products, products we may commercialize or promote in the future, and our therapeutic candidates, being chosen less frequently or the pricing being substantially lowered. At this stage, it is difficult to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us.

These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare, Medicaid, and the State Children's Health Insurance Program), creation of government-sponsored healthcare insurance sources, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for prescribed drugs and pharmaceuticals, including our current commercial products, those we and our development or commercialization partners are currently developing or those that we may commercialize or promote in the future. If reimbursement for the products we currently commercialize or promote, any product we may commercialize or promote, or approved therapeutic candidates is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our reputation, business, financial condition or results of operations.

Extending medical benefits to those who currently lack coverage will likely result in substantial costs to the U.S. federal government, which may force significant additional changes to the healthcare system in the U.S. 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 current commercial products, our development or commercialization partners or any product we may commercialize or promote, or those therapeutic candidates currently being developed by us), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for our current commercial products, any product we may commercialize or promote, or any therapeutic candidate, or for which we receive marketing approval in the future, could have a material adverse effect on our reputation, business, financial condition or results of operations.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, in particular, the ACA, and they continue to litigate various aspects of the legislation. On July 26, 2012, the U.S. Supreme Court generally upheld the provisions of the ACA at issue as constitutional. However, the U.S. Supreme Court held that the legislation improperly required the states to expand their Medicaid programs to cover more individuals. As a result, states have a choice as to whether they will expand the number of individuals covered by their respective state Medicaid programs. Some states have not expanded their Medicaid programs and have chosen to develop other cost-saving and coverage measures to provide care to currently uninsured individuals. Many of these efforts to date have included the institution of Medicaid-managed care programs. The manner in which these cost-saving and coverage measures are implemented could have a material adverse effect on our reputation, business, financial condition or results of operations.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the ACA and judicial challenges have continued. We cannot predict the impact on our business of future legislative and legal challenges to the ACA or other aspects of the Healthcare Reform Law or other changes to the current laws and regulations. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for therapeutics affected by the legislation. From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing coverage, reimbursement, and marketing of pharmaceutical products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

During his time in office, former President Trump supported the repeal of all or portions of the ACA. President Trump also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the ACA 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 ACA to the maximum extent permitted by law. Congress has enacted legislation that repeals certain portions of the ACA, 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 ACA's individual mandate, effective January 1, 2019, as well as the Bipartisan Budget Act of 2018, passed in February 2018, which, among other things, repealed the Independent Payment Advisory Board (which was established by the ACA and was intended to reduce the rate of growth in Medicare spending).

Additionally, in December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the ACA 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 ACA. The Fifth Circuit's decision on the individual mandate was appealed to the U.S. Supreme Court. On June 17, 2021, the Supreme Court held that the plaintiffs (comprised of the state of Texas, as well as numerous other states and certain individuals) did not have standing to challenge the constitutionality of the ACA's individual mandate and, accordingly, vacated the Fifth Circuit's decision and instructed the district court to dismiss the case. As a result, the ACA will remain in-effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business.

The Biden administration also introduced various measures in 2021 focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, in July 2021, the Biden administration released an executive order entitled, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response, on September 9, 2021, HHS released a "Comprehensive Plan for Addressing High Drug Prices" that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. And, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA also authorizes HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. We cannot yet assess the impact that the IRA will have on the pharmaceutical industry, but it is expected to be significant.

There is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the U.S. or the effect of any future legislation or regulation. Furthermore, we cannot predict what actions the Biden administration will implement in connection with the Health Reform Law. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the U.S. in the future, if applicable.

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

Under Innovation Law and IIA's rules and guidelines, a qualifying research and development program may be eligible for grants of up to 50% of the program's approved 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 provide that a company that received IIA grants, or the Recipient Company, is prohibited from manufacturing products developed using these IIA grants outside of Israel (unless the IIA approved grant program includes a pre-determined portion of manufacturing that may be performed outside Israel) without receiving prior approval from the IIA (except for the transfer of less than 10% of the manufacturing capacity in the aggregate in excess of such pre-approved portion (if any), which requires only a notice). If the Recipient Company receives approval to manufacture products developed with IIA's grants outside of Israel in excess of such pre-approved portion (if any), 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 in excess of any pre-approved portion. The Recipient Company may also be subject to accelerated royalty repayment rates;

- *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; and

- *Know-how transfer limitation*. Under the IIA's rules and guidelines, the 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).

TyrNovo received the IIA's approval for the production of NT219's API and final product by certain third-party manufacturers outside of Israel in consideration for (among other things) the future payment of increased royalties as stipulated under the IIA's rules and guidelines and described above.

The IIA's approval is not required for the export of any products resulting from the IIA research or development grants.

As of December 31, 2023, TyrNovo has received grants from the IIA in a total amount of approximately NIS 5.5 million (approximately $1.52 million), no royalties had been paid in respect to the grants received by TyrNovo from the IIA and it had a contingent obligation to the IIA (including interest) of $2.3 million. 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.

The restrictions under the Innovation Law 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. Further, 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). 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.

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, incorporated under the laws of the State of Israel, Kitov USA Inc. (currently inactive), incorporated under the laws of the state of Delaware, Purple Biotech GmbH, incorporated under the laws of Switzerland, and Immunorizon Ltd., incorporated under the laws of the State of Israel, and our majority owned subsidiary TyrNovo, incorporated under the laws of the State of Israel, 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, FameWave and Immunorizon 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 were subleased to a third- party until April 2024, and the third party has an option to extend the lease period for an additional 12 months. 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 that harness the power of the TME to overcome tumor immune evasion and drug resistance. Our oncology pipeline includes: NT219, CM24 and the tribody platform with its leading tribody in development, IM1240.

CM24 is a humanized monoclonal antibody that blocks the interactions of CEACAM1, an immune checkpoint protein that supports tumor immune evasion and survival through multiple pathways. We are conducting a randomized, controlled, open label, multicenter Phase 2 study to investigate CM24 in combination with the anti-PD-1 checkpoint inhibitor nivolumab for the treatment of pancreatic ductal adenocarcinoma (PDAC) when administered in combination with standard of care chemotherapy as a second line treatment, as compared to standard of care chemotherapy. We have entered into a clinical collaboration agreement with Bristol Myers Squibb to evaluate the combination of CM24 with Bristol Myers Squibb's PD-1 inhibitor nivolumab, together with nab-paclitaxel, in patients with pancreatic cancer, for this study. We completed patient enrollment in the study in December 2023, and expect to release interim results in the first half of 2024 and a topline report on the overall study by the end of 2024.

NT219 is a small molecule that simultaneously targets and inhibits IRS1/2 and STAT3, two signal transduction pathways in oncology and the development of cancer drug resistance, as further described below. We conducted a phase 1/2 dose escalation study of NT219 as a single agent in patients with solid tumors and a dose escalation phase of NT219 in combination with cetuximab, for the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck cancer and colorectal adenocarcinoma. In February 2024, we determined the RP2D for NT219. The Phase 1 dose escalation study is being concluded and we plan to commence a Phase 2 study in combination with cetuximab in head and neck cancer in the first half of 2024.

Tribody Platform Technology of conditionally-activated tri-specific antibodies engaging both T cells and NK cells to induce a strong, localized immune response within the TME is in pre-clinical development. A cleavable capping technology confines the compound's therapeutic activity to the local TME, which increases the anticipated therapeutic window in patients. The third arm of the antibody specifically targets the TAA. This technology presents a novel mechanism of action by unleashing both innate and adaptive immune systems at the TME to induce an optimal anti-tumor immune response. IM1240 is the platform's lead tribody in development that targets the 5T4 expressed in a variety of solid tumors and is correlated with advanced disease, increased invasiveness and poor clinical outcomes. The acquired portfolio includes additional early-stage assets, targeting other receptors and TAA. We are conducting preclinical studies with our tribody platform and expect to submit an IND application to the FDA for our first tribody, IM1240, in approximately two years.

In addition, we are seeking the acquisition of additional oncology therapeutic candidates at various stages of development to expand and diversify our portfolio and to leverage our development capabilities. We currently have no binding material 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.

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, 2023, we had an accumulated deficit of approximately $137.5 million.

We plan to fund our future operations through commercialization and/or 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

Research and Development Expenses

Our research and development costs are comprised of basic scientific research, preclinical studies, CMC development, clinical studies and medical research. Our research and development team combine clinical and regulatory development expertise mainly in the United States and Israel, and research and development capabilities of our scientific team in Israel. Our research and development activities are focused on our two oncology therapeutic candidates that are in clinical trials, NT219 and CM24, including CMC, regulatory and clinical development, and our tribody platform with its lead drug candidate, IM1240, which is in the preclinical development stage. A significant portion of our research and development activities, including our preclinical and clinical studies, are performed through subcontractors such as 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 CMC activities and clinical trials. For example, in 2021, we initiated a phase 1b/2 study of CM24, which increased our research and developments expenses in 2021. In 2022, we conducted two clinical studies and expanded the clinical development upon completion of the dose escalation phases in CM24, in addition to CMC activity to support the studies, resulting in an increase of our research and development expenses. In 2023, we initiated a phase 2 study of CM24 and completed patient enrollment in the study in December 2023, in addition to CMC activity to support the studies, resulting in an increase of our research and development expenses.

Research and development expenses also include compensation for our employees and consultants for medical, regulatory and development work. As of December 31, 2023, our research and development staff consisted of 13 full-time employees.

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 and technology.

Set forth below is a summary of the research and development expenses for the years ended December 31, 2023, 2022 and 2021. All the costs in 2023 were incurred in connection with the development of NT219, CM24 and our tribody platform. In 2022 and 2021 all the costs were incurred in connection with the development of NT219 and CM24.

	Year Ended December 31,		
	2023	2022	2021
	(U.S. dollars in thousands)		
Total research and development expenses	17,034	16,320	11,827

In addition to the major cost of preclinical studies, clinical trials, and CMC development, research and development expenses include consulting expenses for regulatory and project management work required for the 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,		
	2023	2022	2021
	(U.S. dollars in thousands)		
Salary and salary related expenses	2,323	2,382	1,721
Share-based payment	768	768	557
Service providers	13,943	13,170	9,549
	17,034	16,320	11,827

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 therapeutic candidates, as well as the availability of resources and based on ongoing assessments of the commercial potential of our therapeutic candidates and other therapeutic candidates we may acquire. In addition, we cannot forecast with any degree of certainty which 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 therapeutic candidates in order to focus our resources on more promising therapeutic candidates or projects. Alternatively, we may elect to allocate more resources towards our current therapeutic candidates than currently anticipated. Completion of preclinical studies and/or clinical trials by us or by our future licensees may last several years or more, although the exact duration generally varies based on the nature, complexity, novelty and intended use of a therapeutic candidate. See "Item 3. Key Information – D. Risk Factors – Risks Related to Our Business, Operations and Regulatory Matters."

The lengthy process of completing CMC and/or preclinical studies and/or clinical trials and seeking regulatory approvals for our 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 insurance premiums, professional fees of external auditors and legal services, travel costs and legal expenses less reimbursement of legal expenses associated with class action claims.

Expenses (income) on account of warrants

Expenses (income) on account of warrants comprises mainly the fair value adjustments of warrants. As more fully described in Note 10, Note 16 and Note 19B to our audited financial statements, the warrants issued in our October 2023 financing were considered a derivative instrument (due to a cashless exercise feature and customary terms in the event of a fundamental transaction) and were recorded as a liability at fair value upon issuance and the fair value is adjusted at any reporting date. The changes in the warrants' fair value are recorded as financial expenses/ income.

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 primarily changes in the fair value of financial liabilities and assets and interest income from funds held in bank deposits.

Discontinued Operation

As previously discussed, COVID-19 adversely impacted the launch of Consensi in the United States, such as the strict measures which did not allow visits of relevant physicians by sales representatives, or by the limited attention by health professionals towards new drugs. In October 2021, the Company agreed, together with its then U.S. distributor for Consensi, Coeptis Pharmaceuticals Inc., to terminate the distribution agreement between the parties. Despite our efforts to identify an alternative distributor for Consensi in the U.S., we concluded that commercialization of Consensi, both in the U.S market and elsewhere, is not likely to generate significant revenue and achieve profitability in the near term. In order to reduce the expenses involved in maintaining the product, we decided to discontinue Consensi-related activities and to allocate the funds to our core oncology-related activities. Accordingly, during 2021, we also terminated the agreements for Consensi concerning the territories of South Korea and China. Consequently, the Company reports Consensi as a discontinued operation. Loss from discontinued operation in 2021 was $0.6 million.

Adjusted Operating loss

Adjusted operating loss is defined as operating loss, plus non-cash share-based compensation expenses and non-cash financial assets evaluation. Our management believes that excluding non-cash charges related to share-based compensation and financial assets evaluation 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 items that are not directly attributable to our core operating performance and that may obscure trends in the core operating performance of the business. Non-IFRS financial measures have limitations as an analytical tool and should not be considered in isolation from, or as a substitute for, our IFRS results. We expect to continue reporting non-IFRS financial measures, adjusting for the items described 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 these and other similar items in the presentation of non-IFRS financial measures should not be construed as an inference that these items are unusual, infrequent or non-recurring. Adjusted operating loss is not a recognized term under IFRS and does 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 International Accounting Standards Board, requires management 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.

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.

Recoverability of Intangible Assets

The Company performs an impairment test relating to its intangible assets with indefinite useful life, comparing its recoverable amount with its carrying amount.

A. Operating Results

Comparison of the Year Ended December 31, 2023, to the Year Ended December 31, 2022

Research and Development Expenses

Research and development expenses for the year ended December 31, 2023, were $17.0 million, an increase of $0.7 million, or 4%, compared to $16.3 million for the year ended December 31, 2022. The increase was mainly due to expenses related to the ongoing NT219 and CM24 clinical trials, offset by a decrease in CMC activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses, net of reimbursement from insurance for legal fees, for the year ended December 31, 2023, were $5.2 million, compared to $6.3 million for the year ended December 31, 2022, a decrease of $1.1 million. The decrease was mainly due to a decrease in salary and salary related costs, share base payment costs and insurance costs.

Operating Loss

Our operating loss for the year ended December 31, 2023, amounted to $22.3 million, a decrease of $0.3 million, or 1.3%, compared to $22.6 million for the year ended December 31, 2022. The decrease was mainly due to the decrease in selling, general and administrative expenses offsets by the increase in research and development expenses.

Adjusted Operating Loss

On a non-IFRS basis, adjusted operating loss for the year ended December 31, 2023, was $20.4 million, an increase of $0.2 million, compared to $20.2 million for the year ended December 31, 2022, mainly due to the increase in research and development expenses (see reconciliation below).

Finance Income, net

Finance income, net for the year ended December 31, 2023, was $2.3 million, compared to $0.8 million for the year ended December 31, 2022. The increase was primarily due to the change in the fair value valuation of warrants.

Net Loss

Net loss for the year ended December 31, 2023, amounted to $20.0 million, or $0.9 per basic and diluted ADS, compared to a net loss of $21.8 million, or $1.20 per basic and diluted ADS, for the year ended December 31, 2022. The decrease in net loss was mainly due to the increase in financial income and decrease in selling, general and administrative expenses.

Comparison of the Year Ended December 31, 2022, to the Year Ended December 31, 2021

Research and Development Expenses

Research and development expenses for the year ended December 31, 2022, were $16.3 million, an increase of $4.5 million, or 38.1%, compared to $11.8 million for the year ended December 31, 2021. The increase was mainly due to expenses related to the ongoing NT219 and CM24 clinical trials, including CMC supporting activity.

Selling, General and Administrative Expenses

Selling, general and administrative expenses, net of reimbursement from insurance for legal fees, for the year ended December 31, 2022, were $6.3 million, compared to $6.1 million for the year ended December 31, 2021, an increase of $0.2 million.

Operating Loss

Our operating loss for the year ended December 31, 2022, amounted to $22.6 million, an increase of $4.7 million, or 26.3%, compared to $17.9 million for the year ended December 31, 2021. The increase was 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, 2022, was $20.2 million, an increase of $4.3 million, compared to $15.9 million for the year ended December 31, 2021, mainly due to the increase in research and development expenses (see reconciliation below).

Finance Income, net

Finance income, net for the year ended December 31, 2022, was $0.8 million, compared to $0.1 million for the year ended December 31, 2021. The increase was primarily due to $0.2 million interest from bank deposits and $0.3 million derivatives fair value valuation.

Net Loss

Net loss for the year ended December 31, 2022, amounted to $21.8 million, or $1.20 per basic and diluted ADS, compared to a net loss of $18.5 million, or $1.01 per basic and diluted ADS, in 2021. The increase in net loss was mainly due to $4.7 million in operating expenses, offset by a decrease of $0.6 million in loss from discontinued operation and an increase in finance income of $0.7 million.

Reconciliation of Adjusted Operating Loss

	For the year ended December 31		
	2023	**2022**	**2021**
	(U.S. dollars in thousands)		
Operating loss for the year	22,271	22,603	17,934
Less ESOP expenses	(1,875)	(2,412)	(2,082)
			-
	20,396	20,191	15,852

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. 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.

In October 2023, we raised $5 million in a registered direct offering of 2,430,000 ADSs and pre-funded warrants to purchase up to 1,917,827 ADS. In addition, in a concurrent private placement, we issued unregistered warrants to purchase up to 4,347,827 ADSs. The warrants have an exercise price of $1.25 per ADS and are immediately exercisable upon issuance for a period of five and one-half years. In connection with the offering and effective upon the closing of the offering, we amended certain existing warrants to purchase up to an aggregate of 631,556 ADSs that were previously issued in June 2020 and June 2018 at exercise prices of $9.00 to $28.00 per ADS, respectively, such that the amended warrants have a reduced exercise price of $1.25 per ADS and an extended term of five and a half years from the closing of the offering.

On June 9, 2021, we entered into the Sales Agreement with Jefferies for the sale of ADSs, pursuant to which we may offer and sell, from time to time, ADSs through our ATM program, with Jefferies acting as our agent. We originally filed a prospectus for a $50.0 million ATM program, but the aggregate offering price was subsequently reduced to $21.0 million on March 23, 2022, and to $3.0 million on October 17, 2023. As of March 3, 2024, we have sold approximately 2,217,325 of our ADSs for total gross proceeds of $4.0 million under the Sales Agreement.

As of December 31, 2023, we had on hand approximately $15.3 million in cash and cash equivalents, and in short-term deposits. We believe that our current cash and cash equivalents are sufficient to satisfy liquidity requirements for at least the next 12 months. Since we do not know whether, if at all, we will generate significant revenues from our therapeutic candidates should we decide to continue the development of our CM24, NT219 and IM1240, 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 our CM24, NT219 and our tribody platform with its leading therapeutic candidate IM1240 therapeutic candidates, including securing commercialization agreements with third parties, favorable pricing and market share;
- 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, 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.

Cash Flow

Operating activities

For the year ended December 31, 2023, net cash used in operating activities from continuing operation was approximately $19.9 million compared to approximately $16.7 million and $14.9 million for the years ended December 31, 2022 and 2021, respectively. The increase of $3.2 million in net cash used in operating activities in 2023 compared to 2022 was due to the net decrease in assets and liabilities. The increase of $1.8 million in net cash used in operating activities from continuing operation in 2022 compared to 2021 was due to an increase in operating losses, net of adjustments, offset by net change in assets and liabilities. The cash used in operating activities consisted of expenses associated with expenses related to the development of NT219, CM24 and our tribody platform with its leading therapeutic candidate IM1240 and to general and administrative expenses.

Investment activities

Net cash provided by investing activities from continuing operation was $13.9 million for the year ended December 31, 2023, compared to $19.9 million and $13.4 million for the years ended December 31, 2022 and 2021, respectively. The decrease in net cash provided by investing activities from continuing operation in 2023 compared to 2022 was mainly due to a decrease in short term deposits and an acquisition of a subsidiary. The increase in net cash provided by investing activities from continuing operation in 2022 compared to 2021 was mainly attributed to a decrease in short-term and long-term deposits of $6.6 million.

Financing activities

Net cash provided by financing activities from continuing operation was $5.4 million for the year ended December 31, 2023, compared to net cash provided by financing activities of $1.1 million and $1.5 million for the years ended December 31, 2022 and 2021. Net cash provided by financing activities from continuing operation for the year ended December 31, 2023, consisted of $4.3 million net proceeds from the October 2023 registered direct offering and $1.3 million net proceeds from our ATM program. Net cash provided by financing activities from continuing operation for the year ended December 31, 2022, primarily reflects the $1.3 million net proceeds from our ATM program. For the year ended December 31, 2021, net cash provided by financing activities from continuing operation primarily reflects $1.2 million net proceeds from the exercise of warrants and $0.5 million net proceeds from our ATM program. The net proceeds from the financing activities in 2023, 2022 and 2021 were used to finance our operating activities.

Discontinued operation activities

For the year ended December 31, 2021, net cash used in discontinued operation was $0.4 million. We did not have any net cash provided by (used in) discontinued operation for the years ended December 31, 2023 and 2022.

As of December 31, 2023, we had no borrowings.

As of December 31, 2023, and as of the date of this Annual Report on Form 20-F, we had no commitments for capital expenditures.

Contractual obligations

We are a party to contractual obligations involving commitments to make payments to third parties. These obligations impact our short-term and long-term liquidity and capital resource needs. Our long-term contractual obligations primarily consist of the lease agreement for our offices, which is in effect until December 31, 2025, with a non-current lease liability of $163,000 as of December 31, 2023 (see "Item 4. Information on the Company – D. Property, Plant and Equipment).

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. It is not possible for us to predict with any degree of accuracy the outcome of our research and development 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. Critical Accounting Estimates

Not applicable.

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.	68	Independent Director and Chairman of the Board
Isaac Israel[(1)(4)]	46	Director
Simcha Rock, CPA, MBA[(2)]	75	Independent Director
Ido Agmon, MBA[(3)(2)]	47	Independent Director
Robert Gagnon[(2)(4)]	50	Independent Director
Suzana Nahum-Zilberberg[(1)(3)(4)]	53	Independent Director
Ori Hershkovitz[(1)]	50	Independent Director
Yael Margolin, M.Sc., Ph.D	70	Independent Director
Gil Efron, CPA, MA	59	Chief Executive Officer
Lior Fhima, CPA, MBA	47	Chief Financial Officer
Hadas Reuveni, Ph.D.	58	Vice President of Research and Development
Michael Schickler, Ph.D.	66	Head of Clinical and Regulatory Affairs
Ido Morpurgo, BS.C, LL.M	52	Vice President of Operations

(1) Member of Nominations Committee
(2) Member of Audit Committee
(3) Member of Compensation Committee
(4) Member of Pricing Committee for the ATM program

Eric Rowinsky, M.D., has served as the 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 and related disorders. Dr. Rowinsky currently serves as consulting Chief Medical Officer and/or advisor for drug development and registrational strategies to several biopharma companies worldwide. Since July 2021, Dr. Rowinsky has served as the Chief Medical Officer of Hummingbird Biotherapeutics, a life-science company. From 2015 to 2021, Dr. Rowinsky served as Executive Chairman of the Board of Directors and President of Inspira, Inc. (formerly Rgenix, Inc) and is currently serving as its President, Chairman of the Scientific Advisory Board, and Director. Dr. Rowinsky also served as the Chief Scientific Officer of Clearpath Development Inc., from 2015-2021, and has served as a consulting Chief Medical Officer of Oncotartis, Inc. since 2018 and as an advisor to 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. Dr. Rowinsky 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, Dr. Rowinsky 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. Dr. Rowinsky 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, ramucirumab, tagraxofusp 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 a member of Purple Biotech's Board since October 2012. Mr. Israel served as our chief executive officer from October 2012 until July 2022 and has served as an advisor to Purple Biotech since October 2022. Mr. Israel served as our Acting Chief Executive Officer from March 2023 to August 2023, during which period Mr. Israel's engagement as an advisor to the Company was suspended. 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 as a member of Purple Biotech's Board since July 2013. Mr. Rock served as our Chief Financial Officer from July 2013 until he retired from such position as of December 31, 2018, and subsequently served as a strategic consultant to us until December 31, 2019. 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.

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 and financial planning, fund-raising and related business development activities. 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 and 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 chief executive officer 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 B.A. degree in Business Administration and Life Sciences from Tel Aviv University, Tel Aviv, Israel, and an MBA degree from the Hebrew University of Jerusalem, Israel.

Robert Gagnon, MBA, has served as a member of Purple Biotech's Board since March 2021. Mr. Gagnon currently serves as Chief Financial Officer of Remix Therapeutics. Prior to that, Mr. Gagnon was Operating Partner of Gurnet Point Capital, a healthcare venture capital and private equity fund. Prior to joining Gurnet Point Capital in 2022, Mr. Gagnon was Chief Financial Officer of Verastem Oncology. Before joining Verastem in 2018, Mr. Gagnon served as the Chief Financial Officer at Harvard Bioscience, Inc. Prior to that, 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 PricewaterhouseCoopers, LLP. Mr. Gagnon holds an M.B.A. degree from the MIT Sloan School of Management and a B.A. degree in accounting from Bentley College.

Suzana Nahum-Zilberberg, MBA, has served as a member of Purple Biotech's Board since May 2021. Ms. Nahum-Zilberberg currently serves as Vice Chairman of the Board of BioLight Life Science, which is traded on the Tel Aviv Stock Exchange, and from 2011 to 2020 served as the chief executive officer of BioLight. Ms. Nahum-Zilberberg also serves as a director at Human Xtention Ltd., Matricelf Ltd. and Nextferm Technologies Ltd., all of which are traded on the Tel Aviv Stock Exchange, and a number of private companies. Prior to joining BioLight, Ms. Nahum-Zilberberg held a number of leadership positions at Teva Pharmaceuticals Industries, including Vice President of Asia and Pacific and Director in the office of the President and chief executive officer. Ms. Nahum-Zilberberg holds a B.A. degree in accounting and economics and an M.B.A. degree, both from Tel Aviv University, a Certified Director degree from Tel Aviv University, and studied at the INSEAD Asian International Executive Program. Ms. Nahum-Zilberberg is a certified public accountant.

Ori Hershkovitz has served as a member of Purple Biotech's Board since December 2021. Mr. Hershkovitz has held various positions in life sciences investment funds over many years. Mr. Hershkovitz serves as a financial advisor to financial institutions in cooperation with Cantor Fitzgerald L.P. since 2023. Mr. Hershkovitz has served as a board member and a senior advisor to private and public biotechnology and healthcare companies since 2010. Mr. Hershkovitz served on the Board of Directors of Matricelf Ltd. (TASE: MTLF) from 2021 to 2023, and from 2013 to 2016 was a member of the Board of Directors of MicroMedic Ltd. (TASE:MCTC) and Medigus Ltd. (Nasdaq: MDGS). From 2015 to 2019, Mr. Hershkovitz served as a Managing Partner and chief investment officer of Nexthera Fund, a healthcare hedge fund based in New York, managing over $400 million in assets. From 2006 to 2014, Mr. Hershkovitz was the Managing Partner and Head of Research at Sphera Fund in Tel Aviv, managing over $700 million in assets. From 2001 to 2006, Mr. Hershkovitz served as Senior Pharmaceutical Equity Analyst at Leader & Co. Investment House Ltd. in Tel Aviv, and from 1999 to 2001, he was a Pharmaceutical Equity Analyst at Ilanot Batucha Investment House Ltd. Mr. Hershkovitz holds a B.A degree in Business Administration and Finance from Tel Aviv University and is a licensed investment advisor.

Dr. Yael Margolin, Ph.D. has served as a member of Purple Biotech's Board since December 2023. Since 2019, Dr. Margolin has served as a board member to several public and private companies in the healthtech industry, including: Point Biopharma Global (NASDAQ: PNT), Scinai Immunotherapeutics (NASDAQ: SCNI), Quris AI, MakeSense, Neovac, Welltech Ventures, Ramot at Tel Aviv University and TAU Ventures by Tel Aviv University. From 2005 to 2019, she served as President, Chief Executive Officer and director of Gamida Cell Ltd. (NASDAQ: GMDA), a clinical stage biopharmaceutical company, leading the company from preclinical development through phase 3 international registration studies. Prior to that, Dr. Margolin was Vice President of Denali Ventures LLC, a venture capital firm focused on healthcare, and a program manager at Teva Pharmaceuticals. Dr. Margolin is a founder of mentoring@8400, a boutique voluntary mentoring program for young chief executive officers in Israel. Dr. Margolin holds a B.Sc. degree in biology and a M.Sc. degree (*cum laude*) both from Tel Aviv University in Israel, a Ph.D. from the Weitzman Institute of Science in Israel and was a post-doctoral associate at the Yale University School of Medicine.

Gil Efron has served as our Chief Executive Offer since July 2022. Prior to that, Mr. Efron served as our President and Chief Financial Officer since June 2021. Prior to that, Mr. Efron served as our Deputy Chief Executive Officer and Chief Financial Officer, from 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 (non-active) in Israel.

Lior Fhima has served as our Chief Financial Officer since November 2022. Before to joining us, Mr. Fhima served as the chief financial officer of Negev Ecology Ltd. from June 2021. Mr. Fhima served as the Director of Finance at Kamada Ltd., a plasma-derived protein therapeutics company from October 2015 to June 2021. Prior to that, Mr. Fhima served as Chief Accounting Officer of G City, Ltd. (formerly Gazit Globe Ltd) from April 2012 to October 2015. Mr. Fhima holds a BA degree in accounting and business management (*magna cum laude*) and an MBA degree, both from the College of Management Academic Studies in Rishon LeZion, Israel. Mr. Fhima was granted a certified public accountant's license in Israel.

Dr. Hadas Reuveni, Ph.D., has served as the Company's Vice President of 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 managed the discovery and the preclinical development of TyrNovo's portfolio since 2005 and has more than two decades of research and development experience in biotechnology. From 2005 to 2012, Dr. Reuveni served as the Chief Executive Officer of NovoTyr Ltd., a biotech start-up company, a predecessor company to TyrNovo, developing small molecules for the treatment of cancer and neurodegenerative diseases, which was established by Dr. Reuveni and Prof. Levitzki in 2005. Dr. Reuveni also founded and served as a director and Chief Scientific Officer of AngioB Ltd., a start-up company that developed GPCR-based agents for multiple indications, between 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 and Regulatory Affairs 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.

Ido Morpurgo has served as the Company's Vice President of Operations since August 2020. 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 B.Sc. 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 in-kind benefits 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, 2023, was approximately $4.1 million (including $1.6 million share-based compensation related costs). As of December 31, 2023, the total amount set aside as an actuarial estimate by us to provide pension, retirement or similar benefits to our officers (we do not provide any such benefits to our directors in such capacities) was in the aggregate amount of approximately $141,000.

Our directors and executive officers hold exemption and indemnification letters and are covered under our director's and officer's liability insurance policy. For information on exemption and indemnification letters granted to our officers and directors, see "Item 6 Directors, Senior Management and Employees—C. Board Practices—Exculpation, Insurance and Indemnification of Directors and Officers".

As of December 31, 2023, (i) options to purchase 15,940,228 of our ordinary shares granted to our officers and directors were outstanding, of which options to purchase 8,603,228 of our ordinary shares have vested; and (ii) 5,187,000 restricted stock units ("RSUs") awarded to our officers and directors were outstanding. For information regarding our 2016 Equity-Based Incentive Plan, see "Item 6. Directors, Senior Management and Employees—E. Share Ownership—2016 Equity-Based Incentive Plan." For information regarding the corporate approvals for officer and director compensation, see "Item 6. Directors, Senior Management and Employees—C. Board Practices—Compensation of Directors and Executive Officers."

Director Compensation

We currently pay our independent and non-executive directors (other than our chairman) an annual fee of $40,000 for services as a member of our Board, 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, on Board committees and/or on the board of directors 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, an annual fee of $60,000 for services as a member of our Board, as Chairman of the Board, for service on any committee of the Board, 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. In addition, we pay Dr. Rowinsky a monthly fee for his service as the chairman of our medical and clinical committee , which was in the amount of $10,000 for the period commencing on April 1, 2022 and until March 31, 2023 (as approved by our shareholders at our annual general meeting held in August 2022), and in the amount of $5,000 for the period commencing on April 1, 2023 and for such additional period at the discretion of the Board (as approved by our shareholders at our annual general meeting held in June 2023).

Each of our Compensation Committee, Board 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.).

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.

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, 2023, 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 expenses[1]	Bonus expenses and accruals	Share-based expenses[2]	Total[3]
Gil Efron	Chief Executive Officer	$ 307,907	76,478	655,957	1,040,342
Dr. Hadas Reuveni	Vice President of Research and Development	$ 218,674	51,143	215,901	485,718
Dr. Michael Schickler	Head of Clinical and Regulatory Affairs	$ 197,206	68,980	216,183	482,369
Lior Fhima	Chief Financial Officer	$ 193,313	32,733	164,694	390,740
Isaac Israel	Director and former Chief Executive Officer	$ 220,963	77,543	83,286	381,792

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-based payments was estimated using the Black and Scholes model.
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.

Employment Agreement with Gil Efron, our Chief Executive Officer

In July 2022, we entered into an employment agreement with Mr. Gil Efron in his capacity as our chief executive officer, which may be terminated by either party upon 90 days' advance notice to the other party. Mr. Efron's terms of engagement as our chief executive officer were approved by our shareholders at our annual general meeting held on August 25, 2022, and include (among other things) the following compensation and benefits:

Monthly Salary: A base monthly gross salary of approximately $24,600 ("Monthly Salary").

Annual Bonus: An annual bonus that shall not exceed six times the Monthly Salary, subject to the achievement of measurable criteria determined by the Compensation Committee and Board on an annual basis, in accordance with our compensation policy, as in effect from time to time.

Special bonus(es) for an M&A Transaction or Commercial Transaction: A special bonus for each M&A Transaction and Commercial Transaction consummated during each calendar year in an amount equal to, in the aggregate in any calendar year, the lesser of (1) an amount equal to six times the Monthly Salary and (2) 1.5% of (y) in the case of an M&A Transaction signed during the term of employment, the Company valuation determined in such M&A Transaction, and (z) in the case of a Commercial Transaction consummated during the term of employment, the estimated revenues to the Company in such Commercial Transaction, and subject to the restrictions set forth in our compensation policy. "*M&A Transaction*" means one or more related transactions of either: (A) a sale (including an exchange), lease, license or any other transfer or disposition of all or substantially all of the Company's shares or assets; or (B) any merger (including, a reverse merger and a reverse triangular merger), reorganization, amalgamation, consolidation or like transaction of the Company with or into another entity in which the holders of the Company's voting power immediately prior to the consummation of such transaction hold less than 50% of the Company's voting power or the voting power of the resulting or surviving entity or acquiring company immediately following the consummation of such transaction. "*Commercial Transaction*" means any commercial agreement entered into by the Company or any of its subsidiaries with estimated revenues to the Company and/or the applicable subsidiary of at least $5,000,000.

Retirement Grant. A retirement grant of six times the Monthly Salary upon termination of Mr. Efron'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.

Leased Car. A leased car with a monthly operational lease cost to the Company that shall not exceed NIS 6,000 (approximately $1,654), grossed up for tax purposes, not including reimbursement of petrol expenses and other car expenses.

Change of Control Provision. Any equity-based awards approved for grant to Mr. Efron (including the options granted to him on May 23, 2022 in his former role as President and Chief Financial Officer), shall include a provision according to which the vesting of any such outstanding equity awards shall accelerate in full upon a change of control, as defined by our Compensation Committee and Board, subject to shareholder approval of any such awards to the extent required in accordance with applicable law.

Equity Award. A one-time grant to Mr. Efron of an equity-based award comprised of options to purchase up to 3,750,000 ordinary shares (equivalent to 375,000 ADSs) and 150,000 RSUs for ordinary shares (equivalent to 15,000 ADSs). The options will have an exercise price of US$0.245. The options and RSUs will vest over a period of three years, with one-third of each of the awards vesting on the first anniversary of the date of the approval of the awards by our Board on July 11, 2022, and an additional 8.33% of each of the awards vesting at the end of each subsequent three-month period thereafter, subject to Mr. Efron's continued engagement by the Company on each applicable vesting date. Any outstanding unexercised options shall expire five years following the date of the approval of the equity awards by our Board. The vesting of any such equity awards that are outstanding shall accelerate in full upon a change of control, as defined by our Compensation Committee and Board. The equity award is subject to our 2016 Plan and the applicable award agreement entered into with Mr. Efron. The equity award was granted pursuant to the capital gains track of Section 102 of the Israel Income Tax Ordinance [New Version] 5721-1961.

For the approval of compensation arrangements with directors and executive officers, see "Item 6. Directors, Senior Management and Employees—C. Board Practices—Compensation of Directors and Executive Officers."

C. Board Practices

Board of Directors

Our Board presently consists of eight directors. All of our directors also serve as directors of our subsidiaries TyrNovo, FameWave and Immunorizon, and Mr. Israel and Mr. Efron serve as directors of Purple Biotech GmbH. Each of Dr. Rowinsky, Mr. Rock, Ms. Margolin, Mr. Gagnon, Mr. Agmon, Ms. Nahum-Zilberberg and Mr. Hershkovitz 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. Accordingly, 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 (within the meaning of NASDAQ and SEC rules), and our Compensation Committee consists of at least two independent directors (within the meaning of NASDAQ rules).

Our directors 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 (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 2024 annual general meeting of shareholders, the appointment of the directors included in the third class (Mr. Israel, Ms. Nahum-Zilberberg and Mr. Hershkovitz) shall end. At our 2025 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 2026 annual general meeting of shareholders, the appointment of the directors included in the second class (Mr. Rock and Ms. Margolin) 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 replace or dismiss a director (in the case of replacement, only if the appointed director is not a corporation) by 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 our voting rights as of the record date established for the applicable general meeting of our shareholders (the "Special Majority"). 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 and our center of management shall be in Israel, unless, in each case, 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 provisions in our amended and restated articles of association regarding the maximum number of directors that may serve on our Board and composition of our Board and the appointment and removal of directors, may be amended only by our shareholders by the Special Majority.

Under the Companies Law, our Board must determine the minimum number of directors who are required to have financial and accounting expertise (as defined in regulations promulgated under the Companies Law). Our Board has determined that we require at least one director with the requisite financial and accounting expertise and that Mr. Rock, Ms. Nahum-Zilberberg, Mr. Hershkovitz 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 in the future be deemed to be a controlling shareholder (as defined in Section 1 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.

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:

- recommend 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;

- monitor 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;

- decide 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 by any person authorized for such supervision, or via any other method approved by the audit committee;

- determine 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;

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

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

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 audit committee also oversees the management and investment of our cash and cash equivalents and makes investment decisions with respect to our financial assets.

Our Board 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 Mr. Ido Agmon, Mr. Rob Gagnon and Mr. Simcha Rock. Mr. Rock serves as the Chairman of the audit committee. Our Board has determined that each member of our audit committee is independent under NASDAQ Listing Rules and the Exchange Act, and that 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 has also determined that each of Robert Gagnon and Simcha Rock are audit committee financial experts as defined by the SEC 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.

Under the NASDAQ Listing Rules, we are required to maintain a compensation committee consisting of at least two independent directors, within the meaning of the NASDAQ Listing Rules.

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; and

- to decide whether to approve the terms of office and employment of directors and officers that require approval of the compensation committee and determining whether to exempt, under certain circumstances, a transaction with our chief executive officer from the approval of the general meeting of our shareholders.

In addition to the roles mentioned above, our compensation committee also makes recommendations to our Board regarding the award of equity-based grants to our employees.

Our Board 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. Ido Agmon, Ms. Nahum-Zilberberg and Mr. Simcha Rock. Mr. Ido Agmon serves as the Chairman of the compensation committee. Our board of directors has determined that each member of our compensation committee is independent under the NASDAQ Listing Rules, including the additional independence requirements applicable to the members of a 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 by a simple majority of shareholder votes provided that either: (i) such majority includes at least a majority of the shares voted by those shareholders who are non-controlling shareholders and do not have a personal interest in the approval of the compensation policy, who are present at the meeting and vote on the matter (excluding abstentions) or (ii) the total number of votes voted 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.

Pursuant to the Israeli Companies Law, the 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. Any amendment to the compensation policy is subject to the same approval requirements.

On June 15, 2023, our shareholders approved our current compensation policy for executive officers and directors (the "Compensation Policy"). The Compensation Policy does not, on its own, grant any rights to our directors or officers. The Compensation Policy includes both long-term and short-term compensation elements.

The Compensation Policy includes a provision relating to the recovery of compensation (clawback) in an instance of a restatement of our financial statements, which in addition to the Israeli law clawback requirements, is intended to comply with the requirements of a recent amendment to the NASDAQ Listing Rules. Under the recovery provision, in the event we are required to prepare an accounting restatement, we may be required to recover from each executive officer and director any amount of incentive-based compensation received by such executive officer or director that exceeds the amount of incentive-based compensation that otherwise would have been received by the officer or director had such compensation been determined based on the restated amounts in the accounting restatement (computed without regard to any taxes paid). The compensation recovery is subject to certain exceptions in cases where our Compensation Committee determined that recovery would be impracticable.

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.

While renewing our Compensation Policy, our Compensation Committee and Board considered numerous factors, including the relevant matters and provisions set forth in the Companies Law, and reviewed various data and other information they deemed relevant, with the advice and assistance of legal and other advisors. Our Compensation Committee and Board also considered benchmark studies of peer companies prepared for us by outside consultants to determine that the various compensation elements in the Compensation Policy are in line with market practice. 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 Exhibit 4.9 to this Annual Report on Form 20-F.

Nominations Committee

In September 2020, our Board established a 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 nominees for election as directors of the Company, and review and evaluate incumbent members of the Board. Our Board elected to rely on the "foreign private issuer exemption" with respect to the composition of our nominations committee and nominations of our directors, and determined that our nominations committee need not be composed solely of independent directors (within the meaning of Nasdaq Listing Rules). Our nominations committee currently consists of Ms. Suzana Nahum-Zilberberg, Mr. Issac Israel and Mr. Eric Rowinsky.

Pricing Committee

In April 2021, our Board established a non-independent pricing committee in connection with the establishment of our ATM program, whose role is to approve sales to be conducted pursuant to the Sales Agreement entered into in connection with the ATM program. Our pricing committee currently consists of Robert Gagnon, Ori Hershkowitz and Isaac Israel. Isaac Israel serves as the Chairman of the pricing 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. Mr. Yisrael Gewirtz, a partner at Fahn Kanne Control Management Ltd., a member firm of Grant Thornton International, serves as our internal auditor.

Fiduciary Duties and Approval of Certain 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 the 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 (within the meaning of the Companies Law, as described below) 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 a personal interest of a relative (as defined in the Companies Law) in a transaction that is not considered an extraordinary transaction (as defined in the Companies Law, as described below).

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, subject to the approval requirements set forth in the Companies Law, provided the transaction is to the company's benefit.

Under the Companies Law, 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, 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, or, in the event either of them has a personal interest in such transaction, by one of our directors who does not have a personal interest in such transaction appointed by our Board for such purpose instead of such interested officer. In the event that both our chief executive officer and chief financial officer have personal interests in such transaction, the approval of two directors appointed by the Board of Directors for such purpose and who do not have personal interests in the approval of such transaction, will be required. 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 for the purpose of presenting the matter, such office holder may be present at the meeting. 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 the 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 provided that the provisions that must be included in, and must be considered while determining the compensation policy according to the Companies Law, have been considered by the compensation committee and the board of directors. If the shareholders of the company do not approve a compensation arrangement with an executive officer that is inconsistent with the company's compensation policy, the compensation committee and board of directors may, in special circumstances, override the shareholders' decision provided each of the compensation committee and board of directors discuss the arrangement again and consider (among other things) the shareholders' objections and provide detailed reasons for their decision. An amendment to an existing compensation arrangement with an office holder who is not a director (other than the chief executive officer) 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 relief regulations promulgated under the Companies Law, non-material amendments to the compensation of 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 provided that: (i) the company's compensation policy provides 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. Our Compensation Policy provides that non-material amendments to the compensation of executive officers who are subordinate to the chief executive officer may be approved solely by the chief executive officer.

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 a chief executive officer who is not a director, 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 and consider (among other things) 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 and other relevant circumstances, and the terms and conditions of such renewal or extension are in accordance with the company's compensation policy.

Approval of the chief executive officers' compensation by the compensation committee and board of directors should be in accordance with the company's compensation policy; however, in special circumstances, compensation terms of a chief executive officer that are inconsistent with such policy may be approved by the compensation committee and board of directors provided that they each have considered the 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. The compensation committee may waive the shareholder approval requirement for the initial engagement terms of a candidate for the chief executive officer position, provided that: (i) the compensation arrangement is consistent with the company's compensation policy, (ii) the chief executive officer candidate did not have a business or employment relationship in the previous two years with the company or a controlling shareholder of the company (and in a company without a controlling officer, a business or employment relationship with the chairman of the board of directors, a substantial shareholder, or the most senior office holder in the company), and (iii) the compensation committee determines that subjecting the approval of the engagement to a shareholder vote would impede the engagement.

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 actions 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, considering the shareholder's position in the company.

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 Israeli 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 procurement of directors' and officers' liability insurance policy without the need for shareholder approval, if it determines that, pursuant to the relief regulations promulgated under the Companies Law, the provision of such insurance coverage to the office holders under our directors and officers liabilities insurance policy is on market terms, 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.

We have issued letters of indemnity (the "Indemnity Letters") to each of our current office holders pursuant to which we undertook to indemnify such office holders to the fullest extent permitted by applicable law, to the extent that these liabilities are not covered by insurance. This indemnification is limited to events determined as foreseeable by our Board based on our activities, as set forth in the Indemnity Letters. According to the Indemnity Letters, the total accumulative sum of indemnification that may be paid by us to all office holders will not exceed a sum equal to 25% of our shareholders' equity according to our latest audited or reviewed consolidated financial statements, as of the date of indemnification. The payment of indemnity amounts will not prejudice the right of office holders to receive insurance coverage benefits. Once we have paid to our office holders the aggregate maximum indemnity amount that we may pay to all our office holders, we will not pay additional indemnity amounts unless the payment of these additional amounts is approved by the authorized corporate bodies according to the applicable law at the time of payment of the additional indemnity sums, and subject to an amendment to our articles of association if required by applicable law at such time.

In addition, we have issued letters of exemption to 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.

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 2017 Motions described in "Item 8. Financial Information – A. Financial Statements and Other Financial Information – Legal Proceedings", pursuant to the Indemnity Letters issued to our directors and officers. In addition, we expect to indemnify Isaac Israel for obligations, including the deductibles for our directors' and officers' liability insurance policy, and we may be required to pay costs and expenses he may incur related to the Atzmon Claim described in "Item 8. Financial Information – A. Financial Statements and Other Financial Information – Legal Proceedings", pursuant to the Indemnity Letter issued to him. 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, 2023, the Company had employees as follows: (i) seven in business development, general and administrative roles; and (ii) thirteen in research and development roles. All of such employees were located in Israel.

As of December 31, 2022, the Company had employees as follows: (i) eight in business development, general and administrative roles; and (ii) twelve in research and development roles. All of such employees were located in Israel other than one employee in business development located in Switzerland.

As of December 31, 2021, the Company had employees (including consultants on a full-time basis) as follows: (i) eight in business development, general and administrative roles; and (ii) eleven in research and development roles. All of such employees were located in Israel other than one employee in research and development, who was located in the United States and one employee in business development who was located in Switzerland.

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 and regulations of 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 legally required minimums.

Israeli law generally requires severance pay, which may be funded by managers' insurance and/or a pension fund, upon the retirement or death of an employee or termination of employment without cause (as defined in the Severance Pay Law, 5723-1963). 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 the national health insurance. We also contribute 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, as required by Israeli law.

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 5, 2024, (i) no officer or director beneficially owned 1% or more of our outstanding ordinary shares, other than Mr. Gil Efron, our Chief Executive Officer, who beneficially owned 5,016,123 of our ordinary shares, representing 1.86% of our ordinary shares as of such date. The number of shares beneficially owned by Mr. Efron, includes 3,953,623 ordinary shares issuable upon exercise of options held by Mr. Efron currently exercisable or which will be exercisable within 60 days of March 5, 2024; and (ii) all officers and directors as a group (13 persons) beneficially owned 16,863,568 of our ordinary shares, representing 6.08% of our ordinary shares as of such date. Such number of ordinary shares includes 11,904,978 ordinary shares issuable upon exercise of options and/or RSUs which will be exercisable or shall vest (as applicable) within 60 days of March 5, 2024.

The beneficial ownership of our ordinary shares 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. We deem ordinary shares issuable pursuant to options or RSUs that are currently exercisable or exercisable or that vest (as applicable) within 60 days of March 5, 2024, if any, to be outstanding and to be beneficially owned by the person holding the options or RSUs 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 265,584,738 ordinary shares (not including 1 share held in treasury) outstanding as of March 5, 2024.

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, 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 (who is entitled to delegate its powers under the 2016 Equity Incentive Plan to the compensation committee or audit committee of our Board) in accordance with applicable laws. The exercise price and vesting period of awards are determined by our Board. As of December 31, 2023, 2,537,128 ordinary shares were reserved for the grant of awards under the 2016 Equity Incentive Plan. Our Board may, subject to any other approvals required under any applicable law, increase or decrease the number of ordinary shares reserved under the 2016 Equity Incentive Plan. As of December 31, 2023, options to purchase 19,218,782 ordinary shares and 5,770,750 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 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 (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 (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 (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 "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 Board may, at any time and from time to time, suspend, terminate, modify or amend the 2016 Equity Incentive 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 by the 2016 Equity Incentive Plan, no suspension, termination, modification or amendment 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. Our Board 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, regarding the granting of awards and the terms of award grants, including option 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.

F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation

There was no erroneously awarded compensation that was required to be recovered pursuant to the clawback provisions under our Compensation Policy during the fiscal year ended December 31, 2023.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares by each person or entity known to us to beneficially own 5% or more of our outstanding ordinary shares.

The beneficial ownership of our ordinary shares 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. We deem ordinary shares issuable pursuant to options or warrants that are currently exercisable or exercisable within 60 days of March 5, 2024 and ordinary shares underlying RSUs that vest within 60 days of March 5, 2024, if any, to be outstanding and to be beneficially owned by the person holding the options warrants or RSUs 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 calculation of beneficial ownership is based on 265,584,738 ordinary shares (not including 1 share held in treasury) outstanding as of March 5, 2024. Each one (1) ADS held represents ten (10) ordinary shares. The data presented is based on information disclosed in public regulatory filings in the U.S., in accordance with applicable laws.

Name	Share Number	Percentage
Armistice Capital, LLC (1)	24,993,840	9.4%

(1) Based solely on, and qualified in its entirety with reference to, a Schedule 13G filed by Armistice Capital, LLC ("Armistice Capital") with the SEC on February 14, 2024. According to the Schedule 13G, Armistice Capital is the investment manager of Armistice Capital Master Fund Ltd. (the "Master Fund"), the direct holder of the ordinary shares, and pursuant to an investment management agreement, Armistice Capital exercises voting and investment power over the ordinary shares held by the Master Fund and thus may be deemed to beneficially own the ordinary shares held by the Master Fund. Mr. Boyd, as the managing member of Armistice Capital, may be deemed to beneficially own the ordinary shares held by the Master Fund. The Master Fund disclaims beneficial ownership of the ordinary shares directly held by it by virtue of its inability to vote or dispose of such securities as a result of its investment management agreement with Armistice Capital. In addition, Armistice Capital holds pre-funded warrants to purchase 1,101,000 additional ADSs that include a 9.99% beneficial ownership limitation and warrants to purchase 4,979,383 additional ADSs that include a 4.99% beneficial ownership limitation.

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.

Changes in Percentage Ownership by Major Shareholders

To our knowledge, the only significant changes in the percentage ownership held by our major shareholders (i.e., shareholders that are the beneficial owners of 5% or more of our ordinary shares) as reported in our Annual Reports on Form 20-F during the past three years, are as follows: (i) the ownership percentage of Armistice Capital Master Fund LLC increased to 5% in March 2020 and decreased to under 5% in May 2020 and increased to 9.9% in October 2023, and (ii) the ownership percentage of Morgan Stanley increased to 5% in February 2021 and decreased to under 5% in April 2021.

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 February 29, 2024, BNY held 246,014,450 ordinary shares in custody representing 92.98% 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

The following is a description of our related party transactions, as defined under Item 7.B of Form 20-F, since January 1, 2021.

Service Agreements with Subsidiaries

Purple Biotech provides services to its wholly owned subsidiaries, FameWave, Purple Biotech GmbH and Immunorizon, and its majority owned subsidiary, TyrNovo (including research and development services, corporate management, business development services, accounting services, legal services and others), and the subsidiaries reimburse Purple Biotech for these services at the rate of cost plus 3% (in the case of FameWave, TyrNovo and Immunorizon) and cost plus 10% (in the case of Purple Biotech GmbH).

Agreements with Directors and Officers

Employment agreements. We have entered into employment agreements with each of our executive officers. See "Item 6. Directors, Senior Management and Employees – B. Compensation".

Options and restricted share units. We have granted options to purchase our ordinary shares and RSUs to our executive officers and directors. We describe our equity-based incentive plan under Item 6. "Directors, Senior Management and Employees - E. Share Ownership 2016 Equity-Based Incentive Plan."

Directors' and officers' exculpation, indemnification and insurance. We have granted exemption and indemnification letters to our officers and directors, and our officers and directors are currently covered by a directors' and officers' liability insurance. See "Item 6. Directors, Senior Management and Employees - C. Board Practices - Exculpation, Insurance and Indemnification of Directors and Officers."

Agreements with Mr. Isaac Israel

Advisor Agreement

Mr. Isaac Israel has been engaged to serve as an advisor to the Company in a 50% capacity, since October 10, 2022 (except from March 2023 to August 2023, during which time Mr. Israel's served as the Company's Acting Chief Executive Officer, as described below). Mr. Israel has served as a director since October 2012 and served as our chief executive officer from October 2012 until July 10, 2022, and his former services agreement with the Company formally terminated on October 10, 2022. As an advisor to the Company, Mr. Israel will actively seek to identify and shall take an active role in the execution of new strategic business initiatives and shall support the Company in its fund-raising activities. The advisory services were provided for an initial period of 12 months, effective as of October 10, 2022, the engagement was automatically extended for a 12-month period and will automatically be extended for successive 12-month periods thereunder, under the same conditions, as detailed below, unless terminated by either party upon 90 days' advance notice to the other party ("Engagement Period"). At our annual general meeting held on August 25, 2022, our shareholders approved the payment of the following compensation to Mr. Israel, in consideration for his service as an advisor:

Monthly Fee. A monthly advisory fee in the amount of $6,700 (plus VAT) (excluding out-of-pocket expenses as approved by the Company) ("Monthly Fee"), payable commencing as of January 10, 2023.

Transaction Bonus(es). Commencing as of October 10, 2022, Mr. Israel will be entitled to the following transaction bonuses: (1) For contribution to the achievement of a Strategic Transaction signed during the Engagement Period: (i) in the event of a transaction under clause (A) or (B) below - 1% of the Company value determined for the transaction; or (ii) in the event of a commercial agreement under clause (C) below - 1% of the cash actually received by the Company or the applicable subsidiary, and subject to the restrictions set forth in our Compensation Policy. "Strategic Transaction" means one or more related transactions of either: (A) sale (including an exchange), lease, license or any transfer or disposition of all or substantially all of the Company's shares or assets; (B) any merger (including, a reverse merger and a reverse triangular merger), reorganization, amalgamation, consolidation or like transaction of the Company with or into another entity in which the holders of the Company's voting power immediately prior to the consummation of such transaction hold less than 50% of the Company's voting power or the voting power of the resulting or surviving entity or acquiring company immediately following the consummation of such transaction; or (C) any commercial agreement entered into by the Company or any of its subsidiaries with estimated revenues to the Company or the applicable subsidiary of at least $5 million. (2) For contribution to the achievement of a financing transaction (excluding a financing under the Company's existing ATM program) closed during the Engagement Period – 1% of the cash actually received by the Company in the applicable financing transaction. In the event of the signing of a Strategic Transaction during the Engagement Period or the closing of a financing transaction (excluding a financing under the Company's existing ATM program) during the Engagement Period, which does not qualify for the above monetary bonus – Mr. Israel shall be entitled to a transaction bonus equal to four times the Monthly Fee. The total transaction bonus(es) will not exceed an annual amount (during any consecutive 12-month period) of $2,000,000.

Other. The above dollar denominated fees, and all other dollar denominated payments will be 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 Monthly Fee is subject to adjustment in the event that a general salary increase ("*tosefet yoker*") is implemented in Israel due to the increase in the Israel consumer price index, under certain circumstances.

Acting Chief Executive Officer

Mr. Israel served as Acting Chief Executive Officer from March 2023 to August 2023, while Mr. Gil Efron, our Chief Executive Officer, was on medical leave. During his service as our Acting Chief Executive Officer, the terms of Mr. Israel's engagement as an advisor to the Company, as described above, were suspended and he was not entitled to additional compensation for service as a non-executive director. At our annual general meeting held on June 15, 2023, our shareholders approved the payment of the following compensation to Mr. Israel in consideration for his service as Acting Chief Executive Officer:

Monthly Fee: A monthly fee in the amount of US$30,000 plus VAT (the "Monthly Fee"), plus out-of-pocket expenses as approved by the Company.

Signing and Retention Bonuses: A cash bonus equal to one Monthly Fee as a signing bonus. In addition, to the extent Mr. Israel would be required to serve as our Acting Chief Executive Officer for a period in excess of six months, he would have been entitled to a cash bonus equal to 1.5 times his Monthly Fee.

Transaction Bonus(es): Mr. Israel was entitled to the same transaction bonuses to which he is entitled in his capacity as an advisor to the Company, as described above.

Car expenses. A monthly payment for car expenses of NIS 5,000 (approximately $1,378).

Other: Dollar denominated payments were to be 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 Monthly Fee was subject to adjustment in the event that a general salary increase ("*tosefet yoker*") is implemented in Israel due to the increase in the Israel consumer price index, under certain circumstances.

Insurance, Indemnification and Exemption. During his service as Acting Chief Executive Officer, Mr. Israel continued to benefit from our directors' and officers' liability insurance policy, as in effect from time to time, and the indemnification and exemption letter agreements that we previously entered into with him.

Medical and Clinical Committee Chairman

Dr. Rowinsky, the chairman of our Board, serves as the chairman of our medical and clinical committee established in March 2022. We pay Dr. Rowinsky a monthly fee for his service as the chairman of our medical and clinical committee, which was in the amount of $10,000 for the period commencing on April 1, 2022 and until March 31, 2023 (as approved by our shareholders at our annual general meeting held in August 2022) and in the amount of $5,000 for the period commencing on April 1, 2023 and for such additional period at the discretion of the Board (as approved by our shareholders at our annual general meeting held in June 2023). The medical and clinical committee's primary responsibilities are to: (i) assist our clinical team in the design, planning and supervision of clinical trials; (ii) support our Head of Clinical and Regulatory Affairs in the medical aspects of clinical trials; (iii) support the Company's Chief Medical Officer; and (iv) assist in the medical and clinical review of potential new business opportunities.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

Consolidated Financial Statements

See Item 18 "Financial Statements."

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) on December 1, 2015. The 2015 Motion was with respect to asserted claims for damages to the holders of our securities listed on the Tel Aviv Stock Exchange, arising due to the 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, had the 2015 Motion been certified as a class action, was approximately NIS 16.4 million (approximately $4.6 million). In addition to this amount, the petitioners in the motion sought 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 then-ongoing formal investigation by the Israeli Securities Authority (respectively, the "ISA Investigation" and the "ISA"). 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 an enforcement arrangement in connection with the ISA Investigation, the stay was lifted. On January 7, 2020, a pre-trial proceeding, prior to evidentiary hearing, took place. On April 27, 2022, the evidentiary hearing took place. On October 10, 2022, the petitioners furnished their summaries, on January 9, 2023, we furnished our summaries and on January 25, 2023, the petitioners furnished their response summaries.

On May 21, 2023, the Court issued its final decision in the 2015 Motion whereby it fully dismissed the lawsuit against the personal defendants as well as the motion to approve the lawsuit as a class action lawsuit pursuant to the Class Action Lawsuits Law 5766-2006, and awarded the Company and other respondents court costs of NIS 43,000 (approximately $12,000).

Separate Lawsuit

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 ($0.4 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 thereunder, at the then 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 it did 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 $0.3 million) and for the purposes of the court fees, the amount claimed was reduced to NIS 750,000 ($0.2 million) (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 Tel Aviv Magistrates 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. As result of the dismissal of the 2015 Motion on May 21, 2023, as described above, the Separate Lawsuit was also dismissed on August 28, 2023.

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 $8.2 million). The court ordered a stay of proceedings due to the then-ongoing ISA Investigation. Following approval of an 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. Following the submission of these responses, and as suggested by the court, the parties attended mediation, but without success. The plaintiffs then filed a motion to submit a new expert opinion as a response to the respondents' claims. The court approved the motion on January 3, 2022. On April 7, 2022, the plaintiffs provided their answers to the respondents' responses, which included a new opinion. Evidentiary hearings took place on November 13, 2022, November 20, 2022, and November 22, 2022. The plaintiffs furnished their summaries on June 8, 2023. The respondents must furnish their summaries no later than March 17, 2024.

The Company rejects the claims in the Surviving Motion. 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.

Atzmon Claim

On November 17, 2022, Fidelity Venture Capital Ltd., a private Israeli company ("Fidelity VC") and Mr. Dror Atzmon, an Israeli resident and citizen believed to be the sole shareholder of Fidelity VC (Mr. Atzmon, together with Fidelity VC, the "Atzmon Plaintiffs"), filed a statement of claim in the Economic Division of the Tel Aviv District Court (the "Atzmon Claim") against the Company and a number of other defendants, including our former chief executive officer. The Atzmon Plaintiffs are seeking damages for approximately NIS 9 million (approximately $2.5 million) in connection with various claims relating to alleged contractual breaches and torts arising from an alleged contractual undertaking for the Company to engage the Atzmon Plaintiffs to provide advisory services to the Company following our initial public offering in the United States and listing on NASDAQ in November 2015. We were served with the statement of claim on January 22, 2023. On August 3, 2023, the court ordered the parties to inform it of their willingness to a mediation process; the parties subsequently agreed to a mediation process, a mediator has been appointed and a mediation meeting is due to be scheduled for March 2024. We reject all the claims presented in the Atzmon Claim. 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, of the Atzmon Claim.

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, subject to the provision of the Companies Law. Payment of dividends may be subject to Israeli withholding taxes. See "Item 10 – Additional Information – E. Taxation – Israeli Tax Considerations and Government Programs" for additional information.

B. Significant Changes

Except as otherwise disclosed in this Annual Report on Form 20-F, no significant change has occurred since December 31, 2023.

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".

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 the 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 no more than 40, but no 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 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 matters 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 matter; or
- the particular matter materially and adversely affects the rights of 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 undertook 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 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 Certain 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 Securities Law, 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

Immunorizon Acquisition

The following is a summary of the material terms of the Immunorizon Share Purchase Agreement dated February 1, 2023 (the "Share Purchase Agreement"). The summary of the material terms of the Share Purchase 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 Share Purchase Agreement and/or the applicable ancillary agreement, which are filed as exhibits to this Annual Report. This summary may not contain all of the information about the Share Purchase Agreement and/or any applicable ancillary that is important to you. We urge you to read carefully the Share Purchase Agreement (including any of its ancillary agreements) in its entirety as these are the legal documents governing the transactions.

Share Purchase Agreement

On February 1, 2023, we entered into the Share Purchase Agreement, pursuant to which we acquired 100% of the issued and outstanding shareholdings from the shareholders of Immunorizon Ltd. and Immunorizon became a wholly-owned subsidiary of the Company.

In consideration for the transfer of 100% of Immunorizon's shares to us and the other obligations set forth in the Share Purchase Agreement, we paid an aggregate purchase price consisting of an aggregate upfront payment of $3.5 million in cash and an aggregate $3.5 million in ADSs, at a price per ADS equal to the NASDAQ volume-weighted average price of our ADSs for the 60-day period preceding the execution date of the agreement the ("PPS"). Additional long-term milestones are set at an aggregate amount of $94 million, with royalties out of net sales. Those long-term milestones include (i) development milestones consisting of pre-clinical and clinical milestones, (ii) regulatory milestones and (iii) sales milestones. The accumulated transaction payments, excluding the upfront payment, will not exceed $100 million.

The ADSs were issued to certain major shareholders of Immunorizon (the "Major Selling Shareholders") and were subject to a three-month lock-up period, and we undertook to file a resale registration statement with the SEC to register the ADSs for resale following the lock-up period, as further described below (see "Lock-Up and Registration Rights Agreement").

In the event that during one year following the closing of the Share Purchase Agreement, the Company enters into an agreement or makes a filing pursuant to which it issues ADSs or other equity securities in a financing transaction (other than under its ATM program used for an accumulated amount of up to $2,000,000 worth of ADSs sold during any 90 days period following the closing of the Share Purchase Agreement, a non-cash transaction or a strategic transaction such as strategic joint venture, pre-clinical or clinical collaboration), at a price per ADS lower than the PPS (such new price, the "New PPS") (a "Dilutive Event"), and at such time a Major Selling Shareholder still holds any ADSs issued to it under the Share Purchase Agreement, the Company shall issue such Major Selling Shareholder additional ADSs ("Additional ADSs") equal to: (i) (A) the number of such ADSs held by such Major Selling Shareholder at such time, multiplied by (B) the PPS divided by (C) the New PPS, minus (ii) the number of such ADSs held by such Major Selling Shareholder at such time. Such protection shall only be provided once. Following the October 2023 registered direct offering, which constituted a Dilutive Event, we issued to the Major Shareholders an aggregate 699,495 Additional ADSs.

Lock-Up and Registration Rights Agreement

At the closing of the transactions contemplated by the Share Purchase Agreement, we entered into a Lock-Up and Registration Rights Agreement (the "Lock-Up and Registration Rights Agreement") with the Major Selling Shareholders under which the Major Selling Shareholders agreed not to, directly or indirectly, in any single transaction or series of related transactions, transfer any of the ADSs issued at the closing of the Share Purchase Agreement during the three-month period following the closing of the Share Purchase Agreement without the prior written consent of the Company (subject to limited exceptions).

In addition, we undertook to file, by no later than 45 days following the closing of the Share Purchase Agreement, a registration statement on Form F-3 with the SEC (the "Registration Statement") registering the resale, following the lock-up period, of the ADSs issued to the Major Selling Shareholders upon the closing of the Share Purchase Agreement and any Additional ADSs issued thereafter (if any). We undertook to use commercially reasonable efforts to keep the resale Registration Statement effective for at least 24 months from the date of the Lock-Up and Registration Rights Agreement (or such shorter period as will terminate when the Major Selling Shareholders cease to hold the ADSs or all of our securities covered by the Registration Statement have been sold or withdrawn). On March 23, 2023, we filed the Registration Statement with the SEC, and it was declared effective on April 5, 2023.

Distribution Agreement with Coeptis

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 provided 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, and 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 were entitled to receive 20% in royalties on net sales of Consensi with minimum royalties of $4.5M over three years. In addition, we were entitled to receive up to $99.5 million in milestone and reimbursement payments, of which $3.5 million was already received and $96 million was subject to certain pre-defined commercial milestones. The agreement was for a term of 15 years and could be extended for additional two-year terms, and included customary provisions, as well as certain residual rights and obligations of the parties, following termination.

In October 2021, we and Coeptis agreed to terminate the distribution agreement and entered into a settlement agreement (the "Settlement Agreement"). In accordance with the Settlement Agreement, Coeptis transferred its remaining inventory of Consensi to the Company and in settlement of Coeptis' outstanding obligations under the distribution agreement, issued to the Company a convertible note (the "Note") in the amount of $1.5 million payable on or before March 2023 (the "Maturity Date") , bearing interest of 5% per annum, which may be converted in whole or in part at any time by the Company into Coeptis shares. The conversion price was set at $5 per share, subject to certain adjustments, under such terms and conditions as agreed between the parties and set forth in the Note, and the conversion price was subsequently reduced to $3 under the Addendum referred to below. Coeptis may prepay the principal amount of the Note plus accrued and unpaid interest at any time prior to the Maturity Date. Coeptis also granted to the Company a warrant, exercisable for a period of three years, to purchase a number of Coeptis shares as set forth therein, with an exercise price that is the same as the conversion price as determined under the Note.

In October 2022, Coeptis announced the completion of its business combination with Bull Horn Holdings Corp., a special purpose acquisition company ("Bull Horn" and the "Merger"). The combined company has been renamed "Coeptis Therapeutics Holdings, Inc." and its public shares began trading on the Nasdaq Global Market. In October 2022, in connection with the consummation of the Merger, we and Coeptis signed an addendum to the Note (the "Addendum") according to which, the Note will remain outstanding following the Merger and shall become an obligation of Bull Horn in accordance with its terms, so that (i) it will automatically become convertible into shares of common stock of Bull Horn instead of shares of common stock of Coeptis, (ii) the number of shares of common stock issuable upon conversion of the Note and the related exercise price will reflect adjustments based on the same exchange ratio of the Coeptis shareholders in connection with the exchange of their shares of Coeptis common stock for shares of common stock in Bull Horn in connection with the Merger, and (iii) section 13(b) of the Note ('Registration Rights') will be read to apply to any future public offering of Bull Horn's common stock. Under the Addendum, Coeptis acknowledged that it consummated a Qualified Offering and that the price per share in such Qualified Offering is $3 per common stock, which led to reduction of the conversion price under the Note to $3.

In July 2023, the Note was amended to extend the Maturity Date to March 31, 2024 and to provide for the repayment of the Note in four installments, with the last installment (including interest) to be paid by March 31, 2024. As of December 31, 2023, Coeptis had paid us an aggregate of $0.9 million under the Note and the outstanding balance of the Note was $0.6 million. During January 2024, Coeptis paid us an additional $0.2 million under the Note.

Other Agreements

For a description of other agreements, please see "Item 3. Key Information – D. Risk Factors – Risks Related to Our Business, Operations and Regulatory Matters", "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."

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

Israeli companies are generally subject to company tax on their taxable income. The Israeli corporate tax rate is 23% since 2018.

Taxation of Shareholders

Capital Gains

Israeli law generally imposes a capital gains tax on the sale of any capital assets by residents of Israel, as defined for Israeli tax purposes, and on the sale of capital assets by a non-resident of Israel if those assets (i) are located in Israel, (ii) are shares or a right to shares in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel, or (iv) a right in a foreign resident corporation, which in its essence is the owner of a direct or indirect right to property located in Israel (with respect to the portion of the gain attributed to the property located in Israel), unless a specific exemption is available or unless a tax treaty between Israel and the shareholder's country of residence provides otherwise. The law distinguishes between real gain and inflationary surplus. The inflationary surplus is a portion of the total capital gain, which is equivalent to the increase of the relevant asset's purchase price, which is attributable to the increase in the Israeli consumer price index between the date of purchase and the date of sale. The real gain is the excess of the total capital gain over the inflationary surplus.

The tax rate applicable to capital gains derived from the sale of the ordinary shares or ADSs, whether listed on a stock market or not, is marginal tax rate according to section 121 of the Israeli Income Tax Ordinance but up to 25% for Israeli individuals, unless such shareholder claims a deduction for financing expenses in connection with such shares, in which case the gain will generally be taxed at a rate of 30%. Additionally, if such shareholder is considered a "significant shareholder" at any time during the 12-month period preceding such sale (i.e., such shareholder holds directly or indirectly, including jointly with others, at least 10% of any means of control in the company) the tax rate will be 30%. However, different tax rates may apply to dealers in securities and shareholders who acquired their shares prior to an initial public offering. Israeli companies are subject to the corporate tax rate as specified in section 126 of the Ordinance on capital gains derived from the sale of shares.

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 a non-Israeli stock exchange (NASDAQ); 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 2018 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.

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 and is subject to certain exemptions under such treaty.

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 663,240 for 2022, NIS 698,280 for 2023 and NIS 721,560 for 2024), 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 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 2023 tax year and we may be classified as a PFIC for the 2024 tax year. If we are indeed so classified for 2023 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.

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.

If we are a PFIC and a U.S. Holder makes a Qualified Electing Fund Election under Section 1295 of the Code ("QEF Election") for the first tax year in which its holding period of its ADSs begins, such U.S. Holder generally will not be subject to the PFIC rules discussed above with respect to its ADSs. However, a U.S. Holder that makes a QEF Election will be subject to U.S. federal income tax on such U.S. Holder's pro rata share of (a) the net capital gain of the Company, which will be taxed as long-term capital gain to such U.S. Holder, and (b) the ordinary earnings of the Company, which will be taxed as ordinary income to such U.S. Holder. Generally, "net capital gain" is the excess of (a) net long-term capital gain over (b) net short-term capital gain, and "ordinary earnings" are the excess of (a) "earnings and profits" over (b) net capital gain. A U.S. Holder that makes a QEF Election will be subject to U.S. federal income tax on such amounts for each tax year in which the Company is a PFIC, regardless of whether such amounts are actually distributed to such U.S. Holder by the Company. However, a U.S. Holder that makes a QEF Election may, subject to certain limitations, elect to defer payment of current U.S. federal income tax on such amounts, subject to an interest charge. If such U.S. Holder is not a corporation, any such interest paid will be treated as "personal interest," which is not deductible.

A U.S. Holder that makes a QEF Election generally (a) may receive a tax-free distribution from the Company to the extent that such distribution represents "earnings and profits" of the Company that were previously included in income by the U.S. Holder because of such QEF Election and (b) will adjust such U.S. Holder's tax basis in the ADSs to reflect the amount included in income or allowed as a tax-free distribution because of such QEF Election. In addition, a U.S. Holder that makes a QEF Election generally will recognize capital gain or loss on the sale or other taxable disposition of ADSs.

The procedure for making a QEF Election, and the U.S. federal income tax consequences of making a QEF Election, will depend on whether such QEF Election is timely. A QEF Election will be treated as timely if it is made for the first year in the U.S. Holder's holding period for the ADSs in which the Company was a PFIC. A U.S. Holder may make a timely QEF Election by filing the appropriate QEF Election documents at the time such U.S. Holder files a U.S. federal income tax return for such year.

A QEF Election will apply to the tax year for which such QEF Election is made and to all subsequent tax years, unless such QEF Election is invalidated or terminated or the IRS consents to revocation of such QEF Election. If a U.S. Holder makes a QEF Election and, in a subsequent tax year, the Company ceases to be a PFIC, the QEF Election will remain in effect (although it will not be applicable) during those tax years in which the Company is not a PFIC. Accordingly, if the Company becomes a PFIC in a subsequent tax year, the QEF Election will be effective, and the U.S. Holder will be subject to the QEF rules described above during a subsequent tax year in which the Company qualifies as a PFIC.

U.S. Holders should be aware that, for each tax year that the Company is a PFIC, the Company can provide no assurances that it will satisfy the record-keeping requirements or make available to U.S. Holders a PFIC Annual Information Statement or any other information such U.S. Holders require to make a QEF Election with respect to the Company or any subsidiary that also is classified as a PFIC.

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.

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.

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 are required 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 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 Form 6-K an interim balance sheet and income statement as of the end of the second quarter of each fiscal year. We have also undertaken under the Sales Agreement for our ATM program to submit to the SEC, on Form 6-K, an interim balance sheet and income statement as of the end of the first and/or third quarters of each fiscal year if we shall desire to sell ADSs pursuant to the Sales Agreement during certain time periods.

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 arise 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 Valley Bank, NY, 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. Furthermore, we manage this risk by hedging our monthly salary expenses denominated in NIS.

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, 2023:

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	11	28	550	(28)	(11)
Other current assets	13	33	660	(33)	(13)
Accounts payable	(5)	(11)	(225)	11	5
Other payables	(27)	(67)	(1,340)	67	27
Post employment benefit liabilities	(3)	(7)	(141)	7	3
Total income (loss)	(11)	(24)		24	11

Set forth below is a sensitivity test to possible changes in U.S. dollars/Euro exchange rate as of December 31, 2023:

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	1	2	48	(2)	(1)
Accounts payable	(3)	(8)	(153)	8	3
Other payables	(5)	(12)	(232)	12	5
Total income (loss)	(7)	(18)		18	7

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 NASDAQ.

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 of December 31, 2023 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) 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, 2023, 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 has determined that each of Mr. Gagnon and Mr. Rock is an "audit committee financial expert" as defined in Item 16A of Form 20-F under the Exchange Act. Our board of directors has also determined that each of the members of our audit committee, Mr. Agmon, Mr. Gagnon and Mr. Rock, qualifies as an independent director under the NASDAQ Listing Rules and satisfies the independence requirements of Rule 10A-3 of the Exchange Act.

ITEM 16B. CODE OF ETHICS

Our Board 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. Our Code is intended to meet the definition of "code of ethics" under Item 16B of 20-F under the Exchange Act. A copy of the Code may be viewed on our 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 on Form 20-F and is not incorporated by reference herein. We will disclose on our website any amendment to, or waiver from, a provision of our Code to the extent required under the rules of the SEC or Nasdaq. There have been no material changes to our Code since our most recent Annual Report Form 20-F.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The consolidated financial statements of at December 31, 2023 and 2022, and for each of the three years in the period ended December 31, 2023, appearing in this Annual Report have been audited by Somekh Chaikin, a member firm of KPMG International (the "Auditor"), independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing. Our Auditor's location is Tel Aviv, Israel, and the Auditor's Firm ID is 1057.

The following table sets forth the approximate total compensation that was expensed by the Company and its subsidiaries to the Auditor, for each of the years ended December 31, 2023 and 2022:

	2023	2022
	(in thousands of U.S. dollars)	
Audit fees [1]	162	145
Tax fees [2]	2	10
Total	164	155

(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.

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

In accordance with the rules of the SEC, Israeli law and our amended and restated articles of association, the appointment of our independent auditors requires the approval of the shareholders of the Company following the approvals of our Audit Committee and Board. Under the Companies Law and our amended and restated articles of association, our shareholders are authorized at an annual general meeting to appoint the Company's independent auditor to hold office until the end of the next annual general meeting or for a longer period that shall not extend beyond the end of the third annual meeting following the annual meeting at which the auditor was appointed. At our 2023 annual general meeting of shareholders, our shareholders appointed Somekh Chaikin, a member of KPMG International, as our independent registered public accounting firm, for a period of three years, until the annual general meeting of shareholders to be held in 2026, 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 services and/or for additional services, 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 Certain 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. Similarly, shareholder approval is required under Israeli law for a private placement that is deemed an "extraordinary private placement" or that involves a director or controlling shareholder. An "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 as required under the NASDAQ Listing Rules.

- *Quorum of Shareholder Meetings.* Under the NASDAQ Listing rules, the minimum 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 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 for selection, director nominees, consistent with criteria approved by the Board.

Except as stated above, we currently 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.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

Not applicable.

Item 16K. CYBERSECURITY

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees; violation of privacy laws and other litigation and legal risk; and reputational risk. We recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data. We currently have security measures in place to protect patients', employees' and vendors' information and prevent data loss and other security breaches, including a cybersecurity risk assessment program. Both management and the Company's Audit Committee are actively involved in the continuous assessment of risks from cybersecurity threats, including prevention, mitigation and detection.

Risk Management and Strategy

Our cybersecurity assessment program outlines policies and procedures and technology we use to oversee and identify risks from cybersecurity threats, and focuses on the following areas:

- *Vigilance*: The Company maintains cybersecurity threat operations with the goal of identifying, preventing and mitigating cybersecurity threats and responding to cybersecurity incidents in accordance with our established disaster recovery policy.

- *Systems Safeguards*: The Company deploys systems safeguards that are designed to protect the Company's information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through ongoing vulnerability assessments and cybersecurity threat intelligence.

- *Third Party Service Provider*: The Company utilizes a third-party service provider to assist the Company to identify, assess, prevent and respond to cybersecurity risks.

- *Training*: The Company provides periodic training for personnel regarding cybersecurity threats, which reinforces the Company's information security policies, standards and practices.

- *Incident Response and Recovery Planning*: The Company has established and maintains a plan that addresses the Company's response to a cybersecurity incident and the recovery from a cybersecurity incident, which plan is evaluated periodically.

- *Communication and Disclosure*: The Company's established plan includes procedures for the communication of cybersecurity incidents so that decisions regarding the disclosure and reporting of such incidents can be made in a timely manner.

- *Governance*: The management's oversight of cybersecurity risk management is supported by the Company's Audit Committee.

Governance

Management is responsible for day-to-day assessment and management of risks from cybersecurity threats, including the prevention, mitigation, detection, and remediation of cybersecurity incidents (if any). The Company's VP of Operations is the member of the Company's management who is principally responsible for overseeing the Company's cybersecurity risk management program. The Company's VP of Operations works in coordination with the other members of management, which includes our Chief Executive Officer, Chief Financial Officer, and General Counsel.

The Company's Audit Committee, in conjunction with management, oversees the assessment of the Company's risks from cybersecurity threats, including prevention and mitigation. The Company's Audit Committee receives periodic updates from the Company's VP of Operations with respect to the management of risks from cybersecurity threats. Additionally, the Audit Committee, in conjunction with management, considers risks from cybersecurity threats as part of its oversight of the Company's business strategy, risk management, and financial oversight.

We engage a third-party consultant to help us assess and identify risks from cybersecurity threats, including the threat of a cybersecurity incident, and assisted us to establish our cybersecurity program and manage our risk assessment program. Our third-party consultant monitors cybersecurity threats to our software.

To date, no risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect our business strategy, results of operations or financial condition. However, an actual or perceived breach of our cybersecurity could damage our reputation, interfere with the progress of our clinical trials and/or our efforts to pursue regulatory approvals for our therapeutic candidates, or subject us to third-party lawsuits, regulatory fines or other actions or liabilities, any of which could adversely affect our business, operating results or financial condition. For further information, see "Item 3. Key Information – D. Risk Factors – Risks Related to Our Industry – *Our business and operations may be materially adversely affected in the event of computer system failures or security or breaches due to cyber-attacks or cyber intrusions, including ransomware, phishing attacks and other malicious intrusions*."

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, 2023 and 2022 and for the three-year period ended December 31, 2023, 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 (incorporated by reference to Exhibit 2.1 to our Annual Report on Form 20-F as filed with the Securities and Exchange Commission on March 9, 2022).
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)
2.3	Form of American Depositary Receipt (included in Exhibit 2.2)
2.4	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)
2.5	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)
2.6	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)
2.7	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)
2.8	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)
2.9	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)
2.10	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)
2.11	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)
2.12	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)
2.13	Form of Pre-Funded Warrant issued to the purchaser in the October 2023 offering (incorporated by reference to Exhibit 4.2 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on October 19, 2023)

2.14	Form of Warrant issued to the purchaser in the October 2023 offering (incorporated by reference to Exhibit 4.3 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on October 19, 2023)
2.15	Form of Amendment to Existing Warrants issued to the purchaser in the October 2023 offering (incorporated by reference to Exhibit 4.4 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on October 19, 2023)
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 (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 20-F as filed with the Securities and Exchange Commission on March 9, 2022)
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)
4.5*	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)
4.6*	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)
4.7	Purple Biotech Ltd. Office Holder Compensation Policy approved the shareholders on June 15, 2023 (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 May 1, 2023)
4.8	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)
4.9	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)
4.10	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)
4.11**	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)
4.12**	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)

4.13	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)
4.14	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)
4.15	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)
4.16	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)
4.17	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)
4.18	Open Market Sale Agreement[SM], dated as of June 9, 2021, by and between the Company and Jefferies LLC (incorporated by reference to Exhibit 1.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on June 9, 2021)
4.19**	Share Purchase Agreement by and among Purple Biotech Ltd., the Shareholders of Immunorizon Ltd. and M. Arkin (1999) Ltd. dated as of February 1, 2023 (incorporated by reference to Exhibit 4.25 to the Registrant's Annual report on Form 20-F furnished to the Securities and Exchange Commission on March 3, 2023
4.20	Form of Securities Purchase Agreement dated as of October 17, 2023 by and between the Registrant and the purchaser in the October 2023 offering (incorporated by reference to Exhibit 4.1 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on October 19, 2023)
4.21	Form of Amendment to Existing Warrants issued to the purchaser in the October 2023 offering (incorporated by reference to Exhibit 4.4 to the Registrant's Form 6-K furnished to the Securities and Exchange Commission on October 19, 2023)
8.1	List of subsidiaries of the Registrant
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
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Confidential treatment granted with respect to portions of this Exhibit.
** Portions of this exhibit has been redacted because it is both not material and is the type that the registrant treats as private or confidential.

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/ Gil Efron
Name: Gil Efron
Title: Chief Executive Officer

By: /s/ Lior Fhima
Name: Lior Fhima
Title: Chief Financial Officer

Date: March 5, 2024

Purple Biotech Ltd.

Consolidated Financial Statements as of December 31, 2023

Purple Biotech Ltd.

Consolidated Financial Statements

As of December 31, 2023

In U.S. Dollars

Index

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Purple Biotech Ltd.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statements of financial position of Purple Biotech Ltd. and its subsidiaries (hereinafter – "the Company") as of December 31, 2023 and 2022, 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, 2023, and the related notes (collectively, "the consolidated financial statements").

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, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2023, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Fair value of intangible assets

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 28,044 thousand as of December 31, 2023. IPR&D is related to the TyrNovo and FameWave acquisitions completed in prior years and the Immunorizon acquisition completed in February 2023. The Company tests its intangible assets for impairment on an annual basis, or more frequently if there are indications of impairment.

We identified the evaluation of the estimated fair value of the intangible assets determined by the Company as part of the annual impairment test as a critical audit matter. Specifically, the evaluation of certain key assumptions into the fair value determination, including future expenses for completing development of the intangible assets, success rates, future revenues, and discount rate, involved a high degree of subjective auditor judgment. Changes in these assumptions could have had a significant effect on the Company's fair value determination.

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 related to the Company's determination of fair value of the intangible assets, including controls related to the key assumptions described above. We assessed the Company's estimate of future expenses by comparing it to budgeted expenses approved by the board of directors and to industry data reports, and inquiring of operations and finance personnel regarding the status of IPR&D efforts. We compared actual expenses for developing the TyrNovo and FameWave IPR&D incurred in the current year to the amounts originally forecasted in order to assess the Company's ability to accurately forecast. We compared the successes rate and future revenues estimated by the Company to industry data reports. We involved valuation professionals with specialized skills and knowledge, who assisted in evaluating the Company's discount rate assumption by assessing the methodology and parameters used in the determination. We performed a sensitivity analysis over the estimated successes rate, future revenues, and discount rate assumptions by considering the effect of a range of potential outcomes.

Somekh Chaikin
Member Firm of KPMG International

We have served as the Company's auditor since 2011.
Tel-Aviv, Israel
March 4, 2024

Consolidated Statements of Financial Position as of December 31,

	Note	2023 USD thousands	2022 USD thousands
Assets			
Cash and cash equivalents	6, 19A	**14,489**	15,030
Short term deposits	19A	**850**	16,652
Other investments	19B	**73**	431
Other current assets	8	**376**	1,143
Total current assets		**15,788**	33,256
Non-current assets			
Right to use assets	7	**316**	467
Fixed assets, net		**154**	215
Intangible assets	5	**28,044**	20,684
Total non - current assets		**28,514**	21,366
Total assets		**44,302**	54,622
Liabilities			
Current maturity of lease liabilities	7	**188**	194
Trade payable		**3,532**	2,132
Other payables	9	**3,463**	4,732
Total current liabilities		**7,183**	7,058
Non-current liabilities			
Lease liability	7	**163**	321
Post-employment benefit liabilities	18	**141**	145
Warrants	19B	**2,518**	-
Total non - current liabilities		**2,822**	466
Equity			
Share capital, no par value		-	-
Share premium	10	**133,184**	126,407
Receipts on account of warrants	10	**28,467**	28,017
Capital reserve for share-based payments	11	**10,088**	10,164
Capital reserve from transactions with related parties		**761**	761
Capital reserve from hedging		**19**	(6)
Capital reserve from transactions with non- controlling interest		**(859)**	(859)
Accumulated loss		**(137,453)**	(117,573)
Equity attributable to owners of the Company		**34,207**	46,911
Non-controlling interests		**90**	187
Total equity		**34,297**	47,098
Total liabilities and equity		**44,302**	54,622

The accompanying notes are an integral part of these consolidated financial statements.

Consolidated Statements of Operations and Other Comprehensive Loss

		For the year ended December 31		
		2023	2022	2021
	Note	USD thousands	USD thousands	USD thousands
Research and development expenses	14	**17,034**	16,320	11,827
Sales, general and administrative expenses	15	**5,237**	6,283	6,107
Operating Loss		**22,271**	22,603	17,934
Change in fair value of warrants	16A	**(3,497)**	-	-
Finance expenses	16B	**2,195**	67	212
Finance income	16B	**(992)**	(910)	(320)
Finance income, net		**(2,294)**	(843)	(108)
Loss for the year from continuing operations		**19,977**	21,760	17,826
Loss from discontinued operation	4	**-**	-	642
Loss for the year		**19,977**	21,760	18,468
Other comprehensive loss:				
Items that will be transferred to profit or loss:				
Loss (profit) from cash flow hedges		(25)	6	-
Total comprehensive loss for the year		19,952	21,766	18,468
Loss attributable to:				
Owners of the Company		**19,880**	21,668	18,384
Non-controlling interests		**97**	92	84
		19,977	21,760	18,468
Total comprehensive loss attributable to:				
Owners of the Company		**19,855**	21,674	18,384
Non-controlling interests		**97**	92	84
		19,952	21,766	18,468
Loss per share data				
Continuing operations				
Basic & diluted loss per ADS - USD		**0.9**	1.20	1.01
Number of ADSs used in calculating basic & diluted loss per ADS		**22,133,294**	18,081,087	17,568,036
Discontinued operation				
Basic & diluted loss per ADS – USD		**-**	-	0.04
Number of ADSs used in calculation		**-**	-	17,568,036

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 hedging	Capital reserve from transactions with related parties	Capital reserve from transactions with Non-controlling interest	Accumulated loss	Total	Non-controlling interests	Total equity
Balance as of January 1, 2023	-	**126,407**	**28,017**	**10,164**	(6)	**761**	**(859)**	**(117,573)**	**46,911**	**187**	**47,098**
Transactions with owners of the Company:											
Issuance of American Depository Shares (ADSs) on the NASDAQ, net of issuance costs	-	**1,045**	**450**	-	-	-	-	-	**1,495**	-	**1,495**
ADS issued in connection with the purchase of a subsidiary (see Note 5C)		**3,781**							**3,781**		**3,781**
Share-based payments	-	**1,951**	-	**(76)**	-	-	-	-	**1,875**	-	**1,875**
Total transactions with owners of the Company		**6,777**	**450**	**(76)**		-	-	-	**7,151**		**7,151**
Loss for the year	-	-	-	-	-	-	-	**(19,880)**	**(19,880)**	**(97)**	**(19,977)**
Other comprehensive profit for the period					**25**				**25**		**25**
Balance as of December 31, 2023	-	**133,184**	**28,467**	**10,088**	**19**	**761**	**(859)**	**(137,453)**	**34,207**	**90**	**34,297**

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 hedging	Capital reserve from transactions with related parties	Capital reserve from transactions with Non-controlling interest	Accumulated loss	Total	Non-controlling interests	Total equity
Balance as of January 1, 2022	**-**	**123,951**	**28,017**	**8,862**	**-**	**761**	**(859)**	**(95,905)**	**64,827**	**279**	**65,106**
Transactions with owners of the Company:											
Issuance of American Depository Shares (ADSs) on the NASDAQ, net of issuance costs	**-**	**1,346**	**-**	**-**	**-**	**-**	-	**-**	**1,346**	-	**1,346**
Share-based payments	**-**	**1,110**	**-**	**1,302**	**-**	**-**	**-**	**-**	**2,412**	**-**	**2,412**
Total transactions with owners of the Company		**2,456**	**-**	**1,302**		-	-	-	**3,758**		**3,758**
Loss for the year	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**(21,668)**	**(21,668)**	**(92)**	**(21,760)**
Other comprehensive loss for the period					(6)				(6)		(6)
Balance as of December 31, 2022	**-**	**126,407**	**28,017**	**10,164**	(6)	**761**	**(859)**	**(117,573)**	**46,911**	**187**	**47,098**

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, 2021	-	118,909	29,984	8,115	761	(859)	(77,521)	79,389	363	79,752
Transactions with owners of the Company:										
Issuance of American Depository Shares (ADSs) on the NASDAQ, net of issuance costs	-	540	-	-	-	-	-	540	-	540
Exercise of warrants	-	3,167	(1,967)	-	-	-	-	1,200	-	1,200
Share-based payments	-	1,335	-	747	-	-	-	2,082	-	2,082
Total transactions with owners of the Company		5,042	(1,967)	747	-	-	-	3,822		3,822
Loss for the year	-	-	-	-	-	-	(18,384)	(18,384)	(84)	(18,468)
Balance as of December 31, 2021	-	123,951	28,017	8,862	761	(859)	(95,905)	64,827	279	65,106

The accompanying notes are an integral part of these consolidated financial statements.

Consolidated Statements of Cash Flows for the year ended December 31,

	2023	2022	2021
		USD thousands	
Cash flows from operating activities from continuing operation:			
Loss for the year from continuing operation	**(19,977)**	(21,760)	(17,826)
Adjustments:			
Depreciation	**197**	201	231
Finance income, net	**(2,294)**	(843)	(108)
Share-based payments	**1,875**	2,412	2,082
	(20,199)	(19,990)	(15,621)
Changes in assets and liabilities:			
Changes in other current assets	**178**	313	(316)
Changes in trade payable	**1,334**	799	399
Changes in other payables	**(1,076)**	2,132	634
Changes in post-employment benefit liabilities	**(162)**	11	27
	274	3,255	744
Net cash used in operating activities from continuing operation	**(19,925)**	(16,735)	(14,877)
Cash flows from investing activities from continuing operation:			
Acquisition of subsidiary, net of cash acquired (see Note 5C)	**(3,549)**	-	-
Proceed from other investments	**875**	-	-
Acquisition of intangible asset	**-**	(202)	-
Decrease in short term deposits	**15,803**	19,658	10,248
Decrease in long term deposits	**-**	160	2,914
Interest received	**755**	324	359
Acquisition of fixed assets	**(3)**	(26)	(115)
Net cash provided by investing activities from continuing operation	**13,881**	19,914	13,406
Cash flows from financing activities from continuing operation:			
Proceeds from issuance of ADSs	**1,563**	1,498	564
ADS issuance expenses paid	**(229)**	(152)	(24)
Proceeds from issuance of ADSs, warrants and prefunded warrants	**5,000**	-	-
Warrants issuance expenses paid	**(661)**	-	-
Proceeds from exercise of warrant	**-**	-	1,200
Repayment of lease liability	**(168)**	(165)	(153)
Interest paid	**(56)**	(67)	(75)
Net cash provided by financing activities from continuing operation	**5,449**	1,114	1,512

	2023	2022	2021
		USD thousands	
Cash flows in respect of discontinued operation as follows:			
Net cash from operating activities	-	-	(374)
Net cash used in discontinued operation	-	-	(374)
Net increase (decrease) in cash and cash equivalents	**(595)**	4,293	(333)
Cash and cash equivalents at the beginning of the year	**15,030**	10,890	11,247
Effect of translation adjustments on cash and cash equivalents	**54**	(153)	(24)
Cash and cash equivalents at end of the year	**14,489**	15,030	10,890

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 developing first-in-class, effective and durable therapies by overcoming tumor immune evasion and drug resistance. The Company focused on Oncology, which includes NT219, a therapeutic candidate which is a small molecule targeting the novel cancer drug resistance pathways IRS1/2 and STAT3, CM24 a monoclonal antibody blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways and a preclinical platform of conditionally-activated tri-specific antibody that engages both T cells and NK cells to mount a strong, localized immune response within the tumor microenvironment. The cleavable capping technology confines the compound's therapeutic activity to the local tumor microenvironment, and thereby potentially increases the anticipated therapeutic window in patients. The third arm specifically targets the Tumor Associated Antigen (TAA). IM1240 is the first tri-specific antibody in development that targets 5T4 expressed in a variety of solid tumors and is correlated with advanced disease, increased invasiveness and poor clinical outcomes.

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 Pharma Ltd. from its shareholders, in exchange for the Company's shares. In December 2020 the Company changed its name from Kitov Pharma Ltd. to Purple Biotech Ltd..

B. The Company's securities (American Depository Shares ("ADS")) were listed for trading on the NASDAQ in November 2015 (including a Series A warrant that expired in November 2020). 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 enable the purchase of 1 ADS.

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.

In October 28, 2021, the Company established a fully owned subsidiary Purple Biotech GmbH (hereinafter "**Purple GmbH**").

In February 2023, the Company acquired 100% of Immunorizon Ltd. (hereinafter "Immunorizon"), see also Note 5C.

The Company together with TyrNovo, FameWave, Immunorizon and Purple GmbH are referred to, in these consolidated financial statements, as "**the Group**".

D. Since incorporation through December 31, 2023, the Group has incurred losses and negative cash flows from operations mainly attributed to its development efforts and has an accumulated loss of USD 137.4 million. The Group has financed its operations mainly through private and public financing rounds. Through December 31, 2023, the Company raised (excluding exercise of warrants) a total of USD 101.5 million net of issuance expenses, see also Note 10.

Management anticipates that its existing capital resources will be adequate to satisfy liquidity requirements for at least the next 12 months. Subsequently, management's plans include pursuing alternative financing arrangements or reducing expenditures as necessary to meet the Company's future cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity.

Note 1 - General (Cont'd)

E. In October 2023, Hamas terrorists (hereinafter: Hamas) infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict.

Any hostilities involving Israel, or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect the Company's operations and results of operations and could make it more difficult for the Company to raise capital. While five study sites out of 27 total study sites in the ongoing studies for CM24 and NT219 are located in Israel, the Company has not yet experienced any material interruptions or delays with respect to such studies, and the Company believes the study sites in Israel have sufficient supply of the therapeutic candidate to continue the studies, as applicable. Both CM24 and NT219 are manufactured by service providers outside of Israel. Most of the research and development work is being conducted by third-party entities outside of Israel. However, a prolonged conflict with Hamas can cause disruptions or delays to the study sites located in Israel, as the result of shortage of staff at study site, resulting in an adverse effect on the Company's business, financial condition and results of operation.

Additionally, all of Company's employees are located and reside in Israel. Shelter-in-place and work-from-home measures, government-imposed restrictions on movement and travel and other precautions that may be taken to address the ongoing conflict may temporarily disrupt the employees' ability to effectively perform the daily tasks.

It is currently not possible to predict the duration or severity of the ongoing conflict or its effects on Company's business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing, and could disrupt Company's business and operations, interrupt the sources and availability of supply and hamper the ability to raise additional funds or sell Company's securities, among others.

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 IFRS Accounting Standard (hereinafter: "IFRS"), as issued by the International Accounting Standard Board ("IASB").

These consolidated financial statements were approved by the board of directors on March 4, 2024.

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. Basis of measurement

The consolidated financial statements have been prepared on the historical cost basis except for the following assets and liabilities:

- Financial instruments and derivatives measured at fair value through profit or loss;
- Provisions;
- Liabilities for employee benefits

For further information regarding the measurement of these assets and liabilities see Note 3 regarding material accounting policies.

Note 2 - Basis of Preparation of the Consolidated Financial Statements (Cont'd)

D. 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
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, success rates (in respect of transition between phases of the R&D of the clinical trials until reaching regulatory approval and marketing) and discount rate.	Impairment of the in-process research and development in profit or loss	See Note 5 regarding Intangible assets

Determination of fair value

Preparation of the financial statements requires the Group to determine the fair value of certain assets and liabilities. 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.

When determining the fair value of an asset or liability, the Group uses market data as much as possible. There are three levels of fair value measurements in the fair value hierarchy that are based on the data used in the measurement, as follows:

- Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: inputs other than quoted prices included in Level 1 that are observable, either directly or indirectly.
- Level 3: inputs that are not based on observable market data (unobservable inputs).

Further information about the assumptions made in measuring fair value of share-based payments, intangible assets and financial instruments are included in Note 11, Note 5 and Note 19, respectively.

Note 2 - Basis of Preparation of the Consolidated Financial Statements (Cont'd)

E. Exchange rates and linkage bases

Balances in foreign currency (mainly the New Israeli Shekel, or NIS) 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, 2023	3.627
December 31, 2022	3.519
December 31, 2021	3.110

	%
Changes in exchange rates for the year ended:	
December 31, 2023	3
December 31, 2022	13
December 31, 2021	(3)

F. Initial application of amendment to standard

Amendment to IAS 1, Presentation of Financial Statements: "Disclosure of Accounting Policies."

According to the amendment, the Company must provide disclosure of their material accounting policies rather than their significant accounting policies. Pursuant to the amendment, accounting policy information is material if, when considered with other information disclosed in the financial statements, it can be reasonably be expected to influence decisions that the users of the financial statements make on the basis of those financial statements. The amendment also clarifies that immaterial accounting policy information need not be disclosed.

The amendment is initially applied in the annual financial statements for 2023.

As a result of applying the Amendment, the extent of the accounting policy disclosure provided in the financial statements for 2023 was reduced and adjusted according to the Company's specific circumstances.

Notes to the Consolidated Financial Statements

Note 3 - Material 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. Acquisition of Subsidiaries

Upon acquisition of subsidiaries, the Company evaluates whether the acquisition is considered a business acquisition or an acquisition of an asset (or group of assets). If the Company reaches the conclusion that the subsidiary acquired is a considered a business, it 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. Transaction costs are expensed as incurred, except if related to the issue of debt or equity securities. If the acquired subsidiary is not considered a business, the Company accounts for the acquisition as a purchase of assets. The Company uses the optional concentration test to determine the accounting treatment of such acquisitions. In applying the concentration test, an entity determines whether substantially all the fair value of the gross assets acquired is concentrated in a single asset or group of similar assets. If so, the asset is not considered a business. As of December 31, 2023, the acquisitions made by the Company were determined to be an acquisition of assets, see Note 5.
Contingent considerations transferred for acquisition of subsidiaries are recorded when the terms and conditions for payment of the consideration are met.

2. Subsidiaries

Subsidiaries are entities controlled by the Group. 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 that are instruments that give rise to a present ownership interest and entitle the holder to a share of net assets in the event of liquidation (for example: ordinary shares), are measured at the date of the business combination at fair value.

Changes in the Group's interest in a subsidiary that do not result in a loss of control are accounted for as equity transactions.

B. Foreign currency transactions

Transactions in foreign currencies are translated to USD which is the functional currency of Group entities at exchange rates at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies at the reporting date are translated to the functional currency at the exchange rate at that date. The foreign currency gain or loss on monetary items is the difference between its cost in the functional currency on date of translation, and the monetary cost in foreign currency translated at the exchange rate at the end of the year.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction.

C. Financial instruments

1. Non-derivative financial assets

Initial recognition and measurement of financial assets

The Group initially recognizes 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.

Subsequent measurement and gains and losses

Financial assets at fair value through profit or loss

These assets are subsequently measured at fair value. Net gains and losses, including any interest income, are recognized in profit or loss.

2. Non-derivative financial liabilities

Non-derivative financial liabilities include: finance lease liabilities, accounts payables and other payables.

Initial recognition of financial liabilities

Financial liabilities are recognized initially on the trade date at which the Group becomes a party to the contractual provisions of the instrument. 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 measurement of financial liabilities

Subsequent to initial recognition these financial liabilities are measured at amortized cost using the effective interest method.

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.

3. Derivative financial instruments

As part of the October 2023 capital raising agreement, the Company issued new warrants and amended previous warrants that were classified as derivative financial instruments.

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.

4. Share capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of ordinary shares and share options are recognized as a deduction from equity.

Incremental costs directly attributable to an expected issuance of an instrument that will be classified as an equity instrument are recognized as an asset in deferred expenses in the statement of financial position. The costs are deducted from equity upon the initial recognition of the equity instruments, or are amortized as financing expenses in the statement of income when the issuance is no longer expected to take place.

5. Issuance of parcel of securities

The consideration received from the issuance of parcel 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.

As part of the October 2023 capital raising, the Company issued pre-funded warrants and amended terms for previous warrants. The Company classified the pre-funded warrants as an equity instrument due to their negligible exercise price.

The amended terms for previously issued warrants increased the fair value of those warrants. The amended terms were part of the capital raising and therefore the Company accounted for the increase in value as issuance cost.

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 involves research for new or substantially improved drug candidates and processes, the manufacturing of such candidates and the pre-clinical and clinical studies for these candidates. 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 ,Famewave, Immunorizion, and asset purchased by Purple GmbH (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 and if any impairment may be needed.

E. Impairment

Timing of impairment testing

The carrying amounts of the Group's non-financial assets, are reviewed at each reporting date to determine whether there is any indication of impairment. If any such indication exists, then the asset's recoverable amount is estimated.

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 intangible assets that have indefinite useful lives.

Measurement of recoverable amount

The recoverable amount of an asset or cash-generating unit is the greater of its value in use and its fair value less costs of disposal. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects the assessments of market participants regarding the time value of money and the risks specific to the asset or cash-generating unit, for which the estimated future cash flows from the asset or cash-generating unit were not adjusted.

Recognition of impairment loss

An impairment loss is recognized if the carrying amount of an asset or cash-generating unit exceeds its estimated recoverable amount. Impairment losses are recognized in profit or loss.

F. Loss per share

The Group presents basic and diluted loss per share data for its ordinary share capital (including pre-funded warrants). 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 year. The loss per share data is presented in the profit and loss statement as loss per ADS giving effect to the number of 10 shares per 1 ADS.

G. 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 pension plans are recognized as an expense in profit or loss in the periods during which related services are rendered by employees.

Short-term employee benefit obligations are measured on an undiscounted basis and are expensed as the related service is provided.

A liability is recognized for the amount expected to be paid under short-term cash bonus if the Group has a present legal or constructive obligation to pay this amount as a result of past service provided by the employee and the obligation can be estimated reliably.

H. Share-based payment transactions

The grant date fair value of share-based payment awards granted to employees is recognized as a salary expense, with a corresponding increase in equity, over the period that the employees become unconditionally entitled to the awards. The amount recognized as an expense in respect of share-based payment awards that are conditional upon meeting service and non-market performance conditions, is adjusted to reflect the number of awards that are expected to vest.

I. 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.

A provision for legal claims is recognized if, as a result of a past event, the Company has a present legal or constructive obligation and it is more likely than not that an outflow of economic benefits will be required to settle the obligation and the amount of obligation can be estimated reliably.

J. Financing income and expense

Finance income comprises changes in the fair value of the financial liability through profit and loss, gains on changes in the fair value of financial assets at fair value through profit or loss and income from short- term and long-term deposits, foreign currency gains, and the reclassification of net gains and losses previously recognized in other comprehensive income on cash flow hedges of foreign currency.

Finance expenses include loss from exchange rate differences and interest fee.

Interest income or 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. 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.

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.

The Company has not recognized deferred tax assets as no future taxable profits are expected in the foreseeable future.

L. Leases

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.

Note 3 - Material Accounting Policies (Cont'd)

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 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.

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 contractual lease period as follows: office lease from September 15 2020 for 5 years and 3.5 months.

M. Discontinued operations

A discontinued operation is a component of the Group's business that represents a separate major line of business that has been disposed of or is held for sale or distribution. Classification as a discontinued operation occurs upon disposal or when the operation meets the criteria to be classified as held for sale, if earlier. When an operation is classified as a discontinued operation, the comparative statement of operation is restated as if the operation had been discontinued from the start of the earliest comparative period.

Note 4 - Discontinued operation

In October 2021, the Company agreed, together with its then U.S distributor for Consensi (an FDA approved fixed-dose combination drug treatment intended for the treatment of osteoarthritis pain and for hypertension, hereinafter "Consensi"), Coeptis Pharmaceuticals Inc., to terminate the distribution agreement. Despite the Company's efforts to identify an alternative distributor for Consensi in the United States., the Company concluded that commercialization of Consensi, both in the U.S market and elsewhere, is not likely to generate significant revenue and achieve profitability in the near term. In order to reduce the expenses involved in maintaining the product, it was concluded to discontinue Consensi activities and to allocate the funds to the Company's core oncology activities. In parallel, the agreements with Kuhnil Pharmaceuticals Inc.'s for the territory of South Korea and Hebei Changshan Biochemical Pharmaceutical Co., Ltd. for the territory of China were terminated. Consensi represented a separate major line of business. Discontinuation also included inventory write off. Consequently, the Company reported Consensi as a discontinued operation and as of December 31, 2021 has one operating segment- oncology.

	2021 USD thousands
Results of discontinued operation	
Revenue	-
Expenses	642
Loss for the year	642
Loss for the year attributable to the owners of the Company:	
From continuing operations	17,826
From discontinued operation	642
Loss per share – Discontinued operation	
Basic & diluted loss per ADS – USD	0.04
Cash flows from discontinued operation	
Net cash used in operating activities	(374)

Notes to the Consolidated Financial Statements

Note 5 - Intangible Assets

As of December 31, 2023, and 2022:

	2023	2022
	USD thousands	
IPR&D related to TyrNovo (see 5A below)	6,172	6,172
IPR&D related to Famewave (see 5B below)	14,310	14,310
IPR&D related to Immunorizon (see 5C below)	7,360	-
IPR&D related to Purple GmbH	202	202
Total intangible assets	28,044	20,684

A Acquisition of Tyrnovo

During the years 2017 to 2019 the Company acquired shares in Tyrnovo, a company developing NT219.

Since 2019 the Company owns 98.47% of Tyrnovo.

B. Acquisition of Famewave

On January 7, 2020 the Company completed the purchase of 100% of FameWave Ltd, a privately held biopharmaceutical Company developing CM24, ("FameWave").

The consideration was recorded based on the fair value of the assets purchased.

C. Acquisition of Immunorizon

In February 2023 the Company completed the acquisition of 100% of Immunorizon Ltd, a privately held biopharmaceutical Company developing potential multispecific T and NK cell engager oncology therapies that selectively activate the immune response within the tumor microenvironment, ("Immunorizon") from its shareholders in consideration of an aggregate upfront payment of $3.5 million in cash, an aggregate of $3.5 million in ADSs (or 2,215,190 ADSs representing ordinary shares at a price per ADS equal to the NASDAQ volume-weighted average price of the Company's ADSs for the 60-day period preceding the execution date of the agreement) with three months lock up period including a price protection mechanism for 12 months (see Note 10D1). Additional future considerations include future payments when achieving certain long-term milestones set at an aggregate amount of $94 million, including royalties on net sales. The acquisition closed on February 15, 2023. The total acquisition amounted to $ 3.6 million.

The acquisition was recorded based on the fair value of the consideration transferred and was accounted for as an asset purchase as it did not meet the definition of a business combination in accordance with IFRS 3.

Note 5 - Intangible Assets (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	44
Intangible asset (1)	7,360
Other receivables	1
Trade payables	(28)
Other payables	(2)
Total net identifiable assets	7,375

(1) Intangible asset - In process research and development

The fair value of the intangible asset recognized at the acquisition date was determined according to the fair value of the issued equity (2,215,190 ADSs) which amounted to USD 3,781 thousand and the cash paid.

According to the agreement, the equity issued included a price protection mechanism as well as a lock up period of three months.

The fair value of equity issued was based on the assumptions below:

a. Share price - 1.59
b. Expected volatility - 70.89%
c. Annual risk-free rate – 4.5%
d. Dividend yield- 0%
e. DLOM – 10.8%

D. As of December 31, 2023, 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 discounted cash flows model considered the risks associated with the clinical/preclinical phase of the intangible assets and the probability of success for each development phase. Certain estimations were determined using industry data reports.

The discount rate used for calculating intangible assets recoverable amount was 18.9%.

The Company performed sensitivity analysis for estimations such as discount rate and royalty rate and concluded that the recoverable amount of the intangible assets exceeds their carrying amount.

Note 6 - Cash and Cash Equivalents

	As of December 31,	
	2023	2022
	USD thousands	
Balance in USD	**14,007**	11,902
Balance in other currencies	**482**	3,128
Total cash and cash equivalents	**14,489**	15,030

Note 7 – Leases

The Group has lease agreements with respect to offices.

A. Information regarding material lease agreements

The Company entered into an agreement for the lease of offices in Rehovot as from September 15, 2020 for a period of 5 years. Accordingly, the Company initially 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. This additional period is not included in the lease payments used-in the calculation of the liability as the Company does not expect it is reasonably certain it will exercise the option. The Company has an option to extend the lease agreements for an additional 5 years at the terms as those of the existing agreement with addition of 5% to the current terms and CPI linked.

B. Right-to-use assets

Carrying amounts of right-to-use assets and change during the period:

	Office lease
	USD thousands
Balance as of January 1, 2023	467
Depreciation on right-to-use assets	(151)
Balance as of December 31, 2023	316
Balance as of January 1, 2022	619
Depreciation on right-to-use assets	(152)
Balance as of December 31, 2022	467

Note 7 - Leases (Cont'd)

C. Lease liability

Maturity analysis of the Company's lease liabilities

	December 31, 2023	December 31, 2022
	USD thousands	USD thousands
Less than one year	**188**	204
One to two years	**188**	388
Total	**376**	592
Current maturities of lease liability	**188**	194
Long-term lease liability	**163**	321

D. Additional information on leases

Amounts recognized in profit or loss

	2023	2022
	USD thousands	USD thousands
Interest expenses on lease liability	**37**	49

Note 8 - Other Current Assets

	As of December 31,	
	2023	2022
	USD thousands	
Government authorities	**171**	146
Prepaid expenses and other receivables	**205**	997
Total other current assets	**376**	1,143

Note 9 - Other Payables

	As of December 31,	
	2023	2022
	USD thousands	
Due to related parties - salary related	**620**	607
Accrued expenses	**2,521**	3,597
Government authorities	**53**	81
Salary related	**269**	437
Other payables	**-**	10
	3,463	4,732

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 21, 2020 the ratio between ADSs and shares was changed from 1:1 to 1:10 (each 1 ADS equal 10 shares).

B. The Company's share capital

	As of December 31, 2023		As of December 31, 2022	
	Number of shares in thousands			
	Authorized	Issued and paid-in	Authorized	Issued and paid-in
Shares, no par value	**1,000,000**	**252,379**	1,000,000	184,815
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		
	2023	**2022**	**2021**
	Number of ADSs in thousands		
Issued as at January 1	**18,482**	17,800	17,211
Issuance of ADSs (See D below and 5C)	**6,388**	544	126
Vesting of RSUs	**368**	138	163
Exercise of warrants	**-**	-	300
Issued as at December 31	**25,238**	18,482	17,800

D. Financing rounds

1. On October 19, 2023, in a registered direct offering on the NASDAQ, the Company raised USD 5 million gross (approximately USD 4.3 million net of placement agent fees). In this registered direct offering, the Company issued an aggregate of 2,430,000 ADSs at a purchase price of USD 1.15 per ADS and pre-funded warrants to purchase up to 1,917,827 ADS. The Company also issued unregistered warrants to purchase up to an aggregate of 4,347,827 ADSs (hereinafter the "October 2023 warrants") which are immediately exercisable, that were recorded as a liability at their fair value at a value of USD 5,348 thousand. The October 2023 warrants have a term of five and a half years and have an exercise price of USD 1.25 per ADS. During 2023, no warrants were exercised.

   In connection with the offering and effective upon October 19, 2023, the Company amended certain existing warrants to purchase up to an aggregate of 631,556 ADSs that were previously issued in June 2020 and June 2018 at exercise prices of $9.00 and $28.00 per ADS, respectively, such that the amended warrants have a reduced exercise price of $1.25 per ADS and an extended term of five and a half years from the closing of the offering. The company recorded USD 761 thousand in issuance expenses in relation to the amendment. During 2023, no warrants were exercised.

   In addition, the Company issued to the placement agent (or its designees) unregistered compensation warrants to purchase up to 304,348 ADSs at a value of USD 357 thousand at an exercise price of USD 1.4375 per ADS. The unregistered placement agent warrants are immediately exercisable and have a term of five years from the date of October 19, 2023.

   In connection with the October 2023 Offering, the Company issued 699,495 ADSs pursuant to an anti-dilution mechanism of that certain Lock-Up and Registration Rights Agreements entered into with former Immunorizon shareholders in connection with the acquisition of Immunorizon in February 2023 (refer to Note 5C).

2. On June 9, 2021, the Company entered into sales agreement with Jefferies LLC, for the sale of ADSs. In accordance with the terms of the sales agreement, the Company may offer and sell ADSs from time to time through Jefferies, acting as the Company's agent. The Company originally filed a prospectus for a $50.0 million "at the market" equity offering program ("ATM Program"), but the aggregate offering price was subsequently reduced to $21.0 million on March 23, 2022, and to $3.0 million on October 17, 2023. During 2023, 2022 and 2021 the Company sold, under the ATM Program, 1,044,040, 543,400 and 126,160 ADSs at an average price of $1.63, $2.65 and $4.46 per ADS and raised USD 1.56 million, USD 1.49 million and USD 0.56 million gross (approximately USD 1.5 million, USD 1.44 million and USD 0.54 million net of placement agent fees), respectively.

Note 10 - Equity (Cont'd)

E. Other equity transactions

1. During 2023, the Company issued 3,680 thousand ordinary shares on account of vested RSUs granted in 2021, 2022 and 2023 to officers, board members and employees.

2. During 2022, the Company issued 1,380 thousand ordinary shares on account of vested RSUs granted in 2020 and 2021 to officers, board members and employees.

3. During 2021, the Company issued 1,634 thousand ordinary shares on account of vested RSUs granted in 2020 to officers, board members and employees.

4. In February 2023 the Company acquired Immunoraizon – see note 5C.

F. Non-controlling interests

The following table summarizes the information relating to Tyrnovo that has non-controlling interests of 1.53%, before any intra-group eliminations:

TyrNovo Ltd.	December 31, 2023	December 31, 2022
	in USD thousands	
Non-current assets	**6**	10
Current assets	**247**	428
Current liabilities	**(23,419)**	(17,240)
Net assets	**(23,166)**	(16,802)
Net assets attributable to non-controlling interests	**(355)**	(258)
Loss for the year	**6,365**	5,983
Loss allocated to non-controlling interests	**97**	92

Note 11 - Share-based Payment Arrangements

A. On March 2, 2023, the board of directors of the Company granted 45 thousand options (to purchase the equivalent of 4,500 ADSs) and 45 thousand RSUs (equivalent to 4,500 ADSs) to an employee. The options have an exercise price of USD 0.198 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 16 thousand.

On April 24, 2023, the board of directors of the Company granted 2,732 thousand options (to purchase the equivalent of 273 thousand ADSs) and 2,732 thousand RSUs (equivalent to 273 thousand ADSs) to the Board members, subject to the approval of the shareholders, and to employees. The options have an exercise price of USD 0.190 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 729 thousand. The board members grant was approved by the shareholders on June 15, 2023.

On October 31, 2022, the board of directors of the Company granted 750 thousand options and 750 thousand RSUs to an employee. The options have an exercise price of USD 0.208 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 267 thousand.

On July 11, 2022, the board of directors of the Company granted 3,750 thousand options and 150 thousand RSUs to the new CEO, subject to approval in the annual general meeting. The options have an exercise price of USD 0.245 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 591 thousand. This grant was approved by the shareholders on August 25, 2022.

On May 23, 2022, the board of directors of the Company granted 6,635 thousand options and 5,885 thousand RSUs to officers and employees. The options have an exercise price of USD 0.304 per one ordinary share, and for certain employee and consultant USD 0.276 per one ordinary share eligible as from June 23, 2022. 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 3,237 thousand.

Note 11 - Share-based Payment Arrangements (Cont'd)

On November 7, 2021, the board of directors of the Company granted 112 thousand options and 112 thousand RSUs to new director, subject to his election in the annual general meeting. The options have an exercise price of USD 0.470 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 73 thousand.

On August 31, 2021, the board of directors of the Company granted 420 thousand options and 420 thousand RSUs to new officer and employee. The options have an exercise price of USD 0.492 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 268 thousand

On June 7, 2021, the board of directors of the Company granted 638 thousand options and 488 thousand RSUs to directors, officers and employees. The options have an exercise price of USD 0.470 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 406 thousand. This grant to directors was approved by the shareholders in December 29, 2021 and the vesting period begun accordingly.

B. The number and weighted average exercise prices (in USD) of share options are as follows:

	Weighted average exercise price			Number of options		
	2023	**2022**	**2021**	**2023**	**2022**	**2021**
Outstanding on January 1	**0.52**	0.97	1.02	**18,468,235**	7,751,303	6,994,377
Expired and forfeited during the year	**0.54**	0.82	1.52	**(2,026,452)**	(418,068)	(413,074)
Granted during the year	**0.19**	0.28	0.47	**2,777,000**	11,135,000	1,170,000
Outstanding on December 31	**0.46**	0.52	0.97	**19,218,782**	18,468,235	7,751,303
Exercisable on December 31	**0.62**	0.97	1.48	**10,923,032**	6,144,318	4,451,430

The exercise price is denominated in NIS and are re-measured using historic exchange rates. Options are exercisable to shares, each ADS represent 10 shares.

Note 11 - Share-based Payment Arrangements (Cont'd)

The options outstanding at December 31, 2023 had an exercise price of USD 0.190- USD 6 (2022 - USD 0.208- USD 6, 2021 -USD 0.346- USD 6), and weighted average contractual life of 3.10 years (2022 – 3.87 years, 2021 – 3.9 years).

C. The number of RSUs are as follows:

	Number of RSUs	
	2023	**2022**
Outstanding at January 1	**7,857,917**	2,610,000
Granted during the year	**2,777,000**	6,785,000
Forfeited during the year	**(1,187,292)**	(157,083)
Vested during the year	**(3,676,875)**	(1,380,000)
Outstanding at December 31	**5,770,750**	7,857,917

Each RSU is convertible to one share, each ADS represent 10 shares.

D. 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**:**

	2023	**2022**
Share Price - USD	**0.160-0.226**	0.213-0.316
Exercise price - USD	**0.19-0.2**	0.208-0.304
Expected volatility (%)	**93.54-96.04**	91.64-96.26
Expected duration (years)	**2-5**	2-5
Dividend yield (%)	**-**	**-**
Risk free rate interest rate (%)	**3.56% -4.31%**	2.90%-4.28%

F. Expenses recognized in the consolidated financial statements:

	For the year ended December 31,		
	2023	**2022**	**2021**
		USD thousands	
Research and development expenses	**768**	768	557
General and administrative expenses	**1,107**	1,644	1,525
Total share-based expense recognized	**1,875**	2,412	2,082

Note 12 - Transactions and Balances with Related Parties

In addition to their salaries or fees, the Group also provides share option programs to directors and officers and contributes to a post-employment defined contribution plan on behalf of employees, see Note 9 for the balances and Note 11 regarding share based payments.

The CEO is entitled to termination benefits of up to 6 monthly salaries or fees, See Note 18.

In addition, the Company pays the chairman of the board a monthly fee for his service as the chairman of our medical and clinical committee, and a monthly fee to one of the directors who has been engaged as an advisor in a 50% capacity.

Note 12 - Transactions and Balances with Related Parties (Cont'd)

Expenses of key management personnel:

The Company recorded expenses to executive officers:

	For the year ended December 31		
	2023	2022	2021
	USD thousands		
Short - term employee benefits	**2,066**	2,623	2,402
Post-employment benefits	**12**	11	27
Share based payments	**1,346**	1,930	1,446
	3,424	4,564	3,875

The Company recorded expenses to directors:

	For the year ended December 31		
	2023	2022	2021
	USD thousands		
Short - term benefits	**427**	448	323
Share based payments	**284**	311	478
	711	759	801

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 , in whole or in part, 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. The recipient company is also obligated to manufacture its drug in Israel unless it receives the approval of the IIA in which case it will be required to pay the higher rate mentioned above. A recipient company is not required to repay the grants if it does not generate revenue.

   TyrNovo's technologies were developed, 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, 2023, the maximum royalty amount that would be payable by TyrNovo, excluding interest, is approximately NIS 5.5 million (USD 1.52 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.

Note 13 - Commitments and contingent liabilities (Cont'd)

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 up to 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.

BIRAD Research & Development Company Ltd. (BIRAD) is entitled to receive a portion of Yissum's royalties on net sales according to an amendment to the License Agreement signed between TyrNovo and Yissum.

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. cCAM Biotherapeutics Ltd. (cCam), a subsidiary of Merck Sharp and Dohme Corp. (MSD), has entered into 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").

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, according to which cCAM assigned to FameWave all its rights, title and interest in, to and under the THM License Agreement. Pursuant to the THM License Agreement, THM and Ramot granted FameWave 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, FameWave 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.

ii) Royalties of three and a half percent (3.5%) of net sales with respect to Biopharmaceutical Products, and royalties of six and a half percent (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.

FameWave 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 a 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 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 expect 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 holders of 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 4.6 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. Preliminary hearings initiated by the court in September 2016 and continued 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 an enforcement arrangement in connection with the ISA investigation, the stay was lifted. On April 27, 2022 the evidentiary hearing took place and thereafter, the parties furnished their summaries and response summaries. On May 21, 2023, the Tel Aviv District Court (Economic Division) dismissed the 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 on December 3, 2015, and ordered the plaintiffs to pay the Company NIS 43,000 in legal expenses.

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 284 thousand) (the "Petition to Exclude"). The Company responded to the court. 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 354 thousand) and for the purposes of the court fees, the amount claimed was reduced to 750,000 NIS (USD 213 thousand) (the "Separate Lawsuit"). In August 2018, the Haifa Magistrates Court transferred the Separate Lawsuit to the Tel Aviv Magistrates Court. 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 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.

   As result of the dismissal of the 2015 Motion on May 21, 2023 as described above, this separate, independent lawsuit files in the Haifa Magistrates Court in May 2018 by a shareholder seeking damages identical to the asserted claims for damages in the 2015 Motion, was also dismissed.

Note 13 - Commitments and contingent liabilities (Cont'd)

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 8.2 million). The court ordered a stay of proceedings due to the then-ongoing ISA Investigation. Following approval of an enforcement arrangement in connection with the ISA investigation, the stay was lifted. The claim is still pending court proceeding.

   In November 2022 an evidence hearing was conducted. On June 8, 2023 the plaintiff's summaries were filed. The respondents must furnish their summaries no later than March 17, 2024.

   The Company rejects the claims in the Surviving Motion. 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.

4. On November 17, 2022, Fidelity Venture Capital Ltd., a private Israeli company ("Fidelity VC") and Mr. Dror Atzmon, an Israeli resident and citizen believed to be the sole shareholder of Fidelity VC (Mr. Atzmon, together with Fidelity VC, the "Atzmon Plaintiffs"), filed a statement of claim in the Economic Division of the Tel Aviv District Court (the "Atzmon Claim") against the Company and a number of other defendants, including our former chief executive officer. The Atzmon Plaintiffs are seeking damages for approximately NIS 9 million (approximately USD 2.5 million) in connection with various claims relating to alleged contractual breaches and torts arising from an alleged contractual undertaking for the Company to engage the Atzmon Plaintiffs to provide advisory services to the Company following the initial public offering in the United States and listing on NASDAQ in November 2015.

   The Company rejects all the claims presented in the Atzmon Claim. On August 3, 2023, the court ordered the parties to inform of their willingness to a mediation process. The parties agreed to a mediation process, a mediator has been appointed and a mediation meeting is due to be scheduled for March 2024. 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, of the Atzmon Claim.

Note 14 - Research and Development Expenses

	For the year ended December 31		
	2023	**2022**	**2021**
	USD thousands		
Salaries, wages and related expenses	**2,323**	2,382	1,721
Share-based payments (see also Note 11)	**768**	768	557
Service providers	**13,943**	13,170	9,549
	17,034	16,320	11,827

Note 15 - Sales, General and Administrative Expenses

	For the year ended December 31		
	2023	**2022**	**2021**
	USD thousands		
Salaries, wages and related expenses	**1,769**	1,845	1,762
Share-based payments (see also Note 11)	**822**	1,333	1,047
Legal fees in connection with ISA investigation and class action lawsuits (see also Note 13B)	**-**	135	12
Reimbursement of legal fees	**(116)**	(63)	(66)
Other professional fees	**1,004**	750	1,222
Board member remuneration and insurance	**818**	1,152	1,033
Board member share-based payments	**284**	311	478
Maintenance expenses	**196**	120	55
Travel and car expenses	**130**	144	133
Depreciation	**199**	201	231
Other	**131**	355	200
	5,237	6,283	6,107

Note 16 - Finance Expense (Income), net

A. Revaluation of warrants

The gain is related to the fair value adjustments of warrants. The 2023 warrants included a cashless exercise feature and customary conditions in case of occurrence of a fundamental transaction. The warrants will expire (unless exercised) within 5.5 years from issuance of those warrants.

B. Finance expenses and income

	For the year ended December 31		
	2023	**2022**	**2021**
	USD thousands		
Finance expenses			
Fees and interest expense	**56**	67	79
Loss from exchange rate differences, net	**13**	-	133
Issuance expenses (see note 10D)	**2,126**	-	-
	2,195	67	212

	For the year ended December 31		
	2023	**2022**	**2021**
	USD thousands		
Finance income			
Interest income from deposits	**(474)**	(532)	(320)
Income from exchange rate differences, net	**-**	(62)	-
Changes in fair value of finance instruments	**(517)**	(245)	-
Other	**(1)**	(71)	-
	(992)	(910)	(320)

Note 17 - Taxes on Income

A. Corporate tax rate

The tax rate applicable to the Group is 23%.

B. Carry-forward losses

The Company and its subsidiaries incurred losses through 2023, which are not expected to be utilized in the foreseeable future. Therefore, the Group did not record current taxes or deferred tax assets.

In 2023, the main reconciling item from the statutory tax rate of the Company (23%, representing theoretical tax benefit of approximately USD 4.6 million) to the effective tax rate (0%) is mainly due to the fact that deferred taxes were not created in respect of current year tax losses and benefits.

The carry-forward loss for tax purposes of the Company and its subsidiaries, and the unrecognized research and development expenses, amounts to USD 96 million as of December 31, 2023 (2022 – USD 82 million, 2021 – USD 59 million).

Notes to the Consolidated Financial Statements

Note 18 - Employee benefits

A. Employee benefits include post-employment benefits and short-term benefits.

Balances include:

	For the Year ended December 31	
	2023	2022
	USD thousands	USD thousands
Short-term benefits	**549**	463
Post-employment benefit liabilities	**141**	145
Post-employment benefit liabilities included in other payables	**-**	158

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		
	2023	2022	2021
	USD thousands	USD thousands	USD thousands
Amount recognized as expense in respect of defined contribution plan	**401**	390	291

C. Certain of the Company's 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 expenses in the amount of USD 446 thousand for the year ended December 31, 2023, USD 406 thousand for the year ended December 31, 2022, and USD 580 thousand for the year ended December 31, 2021.

D. Certain of the Company's 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 141 thousand and USD 303 thousand, as of December 31, 2023 and 2022, respectively.

Notes to the Consolidated Financial Statements

Note 19 - 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 deposits of USD 15,339 thousand at December 31, 2023 (2022 – USD 31,682 thousand). 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 1% - 5.4%.

The carrying amount of cash and cash equivalents and short-term deposits approximate their fair value.

As of December 31, 2023 the group has an amount of USD 139 thousand in short term deposits guaranteed for the Group's leases and credit and am amount of USD 700 thousand in short term deposits guaranteed for hedging transactions.

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.

The Group hedges the foreign currency risk exposure that derives from salary expenses by means of foreign currency derivatives.

In the framework of assessing whether the aforesaid hedging relationships qualify for hedge accounting, the Group applies the mandatory reliefs set forth in the amendments to IFRS 9 *Financial Instruments* and IFRS 7 *Financial Instruments: Disclosures, Interest Rate Benchmark Reform*.

Therefore, as at December 31, 2023 the Group is of the opinion that these hedging relationships continue to qualify for hedge accounting.

Currency risk

The Group is exposed to currency risk mainly for cash and purchases for research and development expenses that are denominated in NIS and EURO. Therefore, the Group is exposed to exchange rate fluctuations in these currencies against the dollar and takes steps to reduce the currency risk by maintaining its liquid resources in accordance with its future needs.

Note 19 - Financial Instruments (Cont'd)

Set forth below is a sensitivity test to possible changes in USD/NIS exchange rate as of December 31, 2023:

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	11	28	550	(28)	(11)
Other current assets	13	33	660	(33)	(13)
Accounts payable	(5)	(11)	(225)	11	5
Other payables	(27)	(67)	(1,340)	67	27
Post-employment benefit liabilities	(3)	(7)	(141)	7	3
Total income (loss)	(11)	(24)		24	11

Set forth below is a sensitivity test to possible changes in USD/ EURO exchange rate as of December 31, 2023:

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	1	2	48	(2)	(1)
Accounts payable	(3)	(8)	(153)	8	3
Other payables	(5)	(12)	(232)	12	5
Total income (loss)	(7)	(18)		18	7

Set forth below is a sensitivity test to possible changes in USD/NIS exchange rate as of December 31, 2022:

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	19	48	960	(48)	(19)
Other current assets	17	42	841	(42)	(17)
Accounts payable	(4)	(10)	(205)	10	4
Other payables	(33)	(83)	(1,668)	83	33
Post-employment benefit liabilities	(3)	(7)	(145)	7	3
Total income (loss)	(4)	(10)		10	4

Set forth below is a sensitivity test to possible changes in USD/ EURO exchange rate as of December 31, 2022:

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	45	112	2,246	(112)	(45)
Accounts payable	(20)	(49)	(979)	49	20
Other payables	(4)	(10)	(207)	10	4
Total income (loss)	21	53		(53)	(21)

B. Financial instruments measured at fair value:

1. In October 2021, the Company received a convertible note in the amount of $1.5 million and a warrant for 300 thousand Coeptis shares as part of Coeptis termination at an exercise price of $5 per warrant. As of December 31, 2023 the outstanding balance of the convertible note was $625 thousands. During January 2024, Coeptis paid an additional $0.2 million under the convertible note.
The warrants are exercisable until September 21, 2024.

   This convertible debt instrument does not meet the solely payments of principal and interest (SPPI) criterion and therefore measured at fair value through profit or loss.

   The fair value of these financial instruments as of December 31,2023 was measured at USD 73 thousand (2022- USD 431 thousand).

Note 19 - Financial Instruments (Cont'd)

2. In October 2023, as part of a registered direct offering, the Company issued 4,347,827 warrants, and amended certain existing warrants to purchase up to an aggregate of 555,555 of the Company's ADSs that were previously issued in June 2020 at exercise prices of $9.00 per ADS such that effective upon the closing of the offering the amended warrants will have a reduced exercise price of $1.25 per ADS and will expire five and a one-half years from the closing date of the offering.

   The warrants were classified as a non-current financial liability as they can be settled in cash on the occurrence of Fundamental Transaction as determined in the agreement. This liability was initially recognized at its fair value on the closing date of the offering and is subsequently accounted for fair value at each balance sheet date and recorded through profit and loss. The fair value of these financial instruments as of December 31,2023 was measured at USD 2,518 thousand

3. Fair value hierarchy of financial instruments measured at fair value:

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
	USD thousands			
Financial asset and liabilities				
Convertible debt instrument and warrant (see Note 19B (1))	-	-	73	73
Financial liability of warrants	-	-	2,518	2,518

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
	USD thousands			
Financial asset				
Convertible debt instrument and warrant (see Note 19B (1))	-	-	431	431

Details regarding fair value measurement at Level 3:

	Financial asset- convertible note	Financial liability- warrant
Balance as of January 1, 2023	431	-
Issuance	-	6,015
Proceed	(875)	-
Revaluation	517	(3,497)
Balance as of December 31, 2023	73	2,518

Financial instrument	Valuation method for determining fair value	Significant unobservable inputs	
For the year ended December 31, 2023			
Warrant (see note 10D1)	Black - Scholes	expected term	5.3 years
		expected volatility	89.94%
		annual risk free interest	3.88%
		dividend yield	0%
Convertible debt instrument		DLOM	26.1%
For the year ended December 31, 2022			
Warrant	Black - Scholes	expected term	1.72 years
		expected volatility	117.42%
		annual risk free interest	4.47%
		dividend yield	0%
Convertible debt instrument		DLOM	37.6%

Note 20 - Subsequent Events

On February 6, 2024 the Company issued 816,827 ADSs due to an exercise of 816,827 October 2023 prefunded warrants (see Note 10D1).

Exhibit 8.1

Purple Biotech Ltd.

The following table sets forth the list of our subsidiaries, including the name, jurisdiction of incorporation and the proportion of our ownership interest, as of the date hereof.

Name of Subsidiary	Jurisdiction of Incorporation	Ownership
Tyrnovo Ltd.	Israel	98.47%
Kitov USA Inc.*	Delaware	100%
FameWave Ltd.	Israel	100%
Purple Biotech GmbH	Switzerland	100%
Immunorizon Ltd.	Israel	100%

* Kitov USA Inc., established in 2019, is currently inactive.

Exhibit 12.1

CERTIFICATION OF THE CHIEF EXECUTIVE 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 5, 2024

/s/ Gil Efron
Gil Efron
Chief Executive Officer

Exhibit 12.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lior Fhima, 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 5, 2024

/s/ Lior Fhima
Lior Fhima
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, 2023, 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 5, 2024

/s/ Gil Efron
Gil Efron
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, 2023, 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 5, 2024

/s/ Lior Fhima
Lior Fhima
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

We consent to the incorporation by reference in registration statements No. 333-226195, No. 333-233793, No. 333-233795, No. 333-238229, No. 333-239807, No. 333-268710 and No. 333-270769 on Form F-3, registration statements, No. 333-235729 and 333-275216 on Form F-1, and registration statements No. 333-211478, No. 333-218538, No. 333-230584, No. 333-238481 and No. 333-264107 on Form S-8 of our report dated March 4, 2024, with respect to the consolidated financial statements of Purple Biotech Ltd. and its subsidiaries.

Somekh Chaikin
Member Firm of KPMG International

Tel Aviv, Israel
March 4, 2024