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

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended December 31, 2021

OR

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

OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) of the Securities Exchange Act of 1934

Date of event requiring this shell company report

For the transition period from _____ to _____

Commission file number 001-35223

BioLineRx Ltd.

(*Exact name of Registrant as specified in its charter*)

Translation of Registrant's name into English

Israel	**2 HaMa'ayan Street Modi'in 7177871, Israel**
(Jurisdiction of incorporation or organization)	*(Address of principal executive offices)*

Philip A. Serlin
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2 HaMa'ayan Street
Modi'in 7177871, Israel
(*Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person*)

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

Title of each class	**Name of each exchange on which registered**
American Depositary Shares, each representing 15 ordinary shares, par value NIS 0.10 per share	Nasdaq Capital Market
Ordinary shares, par value NIS 0.10 per share	Nasdaq Capital Market*

*Not for trading; only in connection with the registration of American Depositary Shares.

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 December 31, 2021: 715,156,008 ordinary shares Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

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

Yes ☐ No ☒

Note — Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

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 and post such files).

Yes ☒ No ☐

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

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

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

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

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

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

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

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

☐ 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 ☒

INTRODUCTION

Certain Definitions

In this Annual Report on Form 20-F, unless the context otherwise requires:

- references to "BioLineRx," the "Company," "us," "we" and "our" refer to BioLineRx Ltd., an Israeli company, and its consolidated subsidiaries;
- references to "ordinary shares," "our shares" and similar expressions refer to the Company's ordinary shares, NIS 0.10 nominal (par) value per share;
- references to "ADS" or "ADSs" refer to the Company's American Depositary Shares;
- references to "dollars," "U.S. dollars" and "$" are to United States Dollars;
- references to "shekels" and "NIS" are to New Israeli Shekels, the Israeli currency;
- references to the "Companies Law" are to Israel's Companies Law, 5759-1999, as amended; and references to the "SEC" are to the U.S. Securities and Exchange Commission.

Forward-Looking Statements

Some of the statements under the sections entitled "Item 3. Key Information – Risk Factors," "Item 4. Information on the Company" and "Item 5. Operating and Financial Review and Prospects" and elsewhere in this Annual Report on Form 20-F constitute 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 are 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 that we have not independently verified. You should not put undue reliance on any forward-looking statements. Our actual results could differ materially from those discussed in the 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. Readers are encouraged to consult the Company's filings made on Form 6-K, which are periodically filed with or furnished to the SEC.

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 preclinical studies, clinical trials and other therapeutic candidate development efforts;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory approvals for our therapeutic candidates and the timing of other regulatory filings and approvals;
- the clinical development, commercialization and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate collaborations;

- our ability to integrate new therapeutic candidates and new personnel;
- 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 and 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, future revenues, capital requirements and our needs for and ability to access sufficient additional financing;
- risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere;
- competitive companies, technologies and our industry;
- statements as to the impact of the political and security situation in Israel on our business; and
- the impact of the COVID-19 pandemic and the Russian invasion of Ukraine, which may exacerbate the magnitude of the factors discussed above.

PART I.

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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, before deciding to invest in our ordinary shares and ADSs. These material risks could adversely impact our results of operations, possibly causing the trading price of our ordinary shares and ADSs to decline, and you could lose all or part of your investment.

Summary Risk Factors

Investing in our ordinary shares involves a high degree of risk, as fully described below. The principal factors and uncertainties that make investing in our ordinary shares risky, include, among others:

Risks Related to Our Financial Condition and Capital Requirements

- We are a clinical-stage biopharmaceutical development company with a history of operating losses, expect to incur additional losses in the future and may never be profitable;
- We cannot assure investors that our existing cash and investment balances will be sufficient to meet our future capital requirements.

Risks Related to Our Business and Regulatory Matters

- If we or our licensees are unable to obtain U.S. and/or foreign regulatory approval for our therapeutic candidates, we will be unable to commercialize our therapeutic candidates.
- Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- Even if we obtain regulatory approvals, our therapeutic candidates will be subject to ongoing regulatory review and if we fail to comply with continuing U.S. and applicable foreign regulations, we could lose those approvals and our business would be seriously harmed.
- We generally depend on out-licensing arrangements for late-stage development, marketing and commercialization of our therapeutic candidates.
- If we cannot meet requirements under our in-license agreements, we could lose the rights to our therapeutic candidates, which could have a material adverse effect on our business.
- If we do not meet the requirements under our agreement with the Agalimmune selling shareholders, we could lose the rights to the therapeutic candidates in Agalimmune's pipeline, including, but not limited to, AGI-134.
- We seek to partner with third-party collaborators with respect to the development and commercialization of motixafortide, and we may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.
- We have no experience selling, marketing or distributing products and no internal capability at present to do so.
- Our business is subject to risks arising from a widespread outbreak of an illness or any other communicable disease, or any other public health crisis, such as the COVID-19 pandemic, which has impacted and could continue to impact our business. Modifications to our therapeutic candidates, or to any other therapeutic candidates that we may develop in the future, may require new regulatory clearances or approvals or may require us or our licensees, as applicable, to recall or cease marketing these therapeutic candidates until clearances are obtained.
- If our competitors develop and market products that are more effective, safer or less expensive than our current or future therapeutic candidates, our prospects will be negatively impacted.
- We have no experience selling, marketing or distributing products and no internal capability at present to do so.
- Our business could suffer if we are unable to attract and retain key employees.

Risks Related to Our Industry

- Even if our therapeutic candidates receive regulatory approval or do not require regulatory approval, they may not become commercially viable products.
- Healthcare reforms and related reductions in pharmaceutical pricing, reimbursement and coverage by governmental authorities and third-party payors may adversely affect our business.
- If third-party payors do not adequately reimburse customers for any of our therapeutic candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase.
- Our business has a substantial risk of clinical trial and product liability claims. If we are unable to obtain and maintain appropriate levels of insurance, a claim could adversely affect our business.
- Significant disruptions of our information technology systems or breaches of our data security could adversely affect our business.

Risks Related to Intellectual Property

- Our access to most of the intellectual property associated with our therapeutic candidates results from in-license agreements with biotechnology companies and a university, the termination of which would prevent us from commercializing the associated therapeutic candidates.
- Patent protection for our products is important and uncertain.
- 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.
- Legal proceedings or third-party claims of intellectual property infringement may require us to spend substantial time and money and could prevent us from developing or commercializing products.
- We may be subject to other patent-related litigation or proceedings that could be costly to defend and uncertain in their outcome.

Risks Related to our Ordinary Shares and ADSs

- We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine.
- The market prices of our ordinary shares and ADSs are subject to fluctuation, which could result in substantial losses by our investors.
- Future sales of our ordinary shares or ADSs could reduce the market price of our ordinary shares and ADSs.
- Raising additional capital by issuing securities may cause dilution to existing shareholders.

Risks Related to our Operations in Israel

- We conduct our operations in Israel and therefore our results may be adversely affected by political, economic and military instability in Israel and its region.
- Due to a significant portion of our expenses and revenues being denominated in non-dollar currencies, our results of operations may be harmed by currency fluctuations.
- We have received Israeli government grants for certain research and development expenditures. The terms of these grants may require us to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. We may be required to pay penalties in addition to repayment of the grants.
- Provisions of Israeli law may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.
- It may be difficult to enforce a U.S. judgment against us and our officers and directors in Israel or the United States, or to serve process on our officers and directors.
- Your rights and responsibilities as a shareholder will be governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. companies.

Risks Related to Our Financial Condition and Capital Requirements

We are a clinical-stage biopharmaceutical development company with a history of operating losses, expect to incur additional losses in the future and may never be profitable.

We are a clinical-stage biopharmaceutical development company that was incorporated in 2003. Since our incorporation, we have been mainly focused on research and development. We have incurred losses since inception, principally as a result of research and development and general administrative expenses in support of our operations. We recorded net losses of $25.4 million in 2019, $30.0 million in 2020 and $27.1 million in 2021. As of December 31, 2021, we had an accumulated deficit of $305.0 million. We anticipate that we will incur significant additional losses as we continue to focus our resources on prioritizing, selecting and advancing our most promising therapeutic candidates. We may never be profitable, and we may never achieve significant sustained revenues.

We cannot assure investors that our existing cash and investment balances will be sufficient to meet our future capital requirements.

As of December 31, 2021, we held cash and short-term investments of $57.1 million. Based on our current projected cash requirements, we believe that our existing cash and investment balances and other sources of liquidity, not including potential milestone and royalty payments under potential out-licensing and other collaboration agreements, will be sufficient to meet our capital requirements into the first half of 2024. We have funded our operations primarily through public and private offerings of our securities, payments received under our strategic licensing and collaboration arrangements and interest earned on investments. The adequacy of our available funds to meet our operating and capital requirements will depend on many factors, including: the number, breadth, progress and results of our research, product development and clinical programs; the costs and timing of obtaining regulatory approvals for any of our therapeutic candidates; the terms and conditions of in-licensing and out-licensing therapeutic candidates; and costs incurred in enforcing and defending our patent claims and other intellectual property rights.

While we expect to continue to explore alternative financing sources, including the possibility of future securities offerings and government funding, we cannot be certain that in the future these liquidity sources will be available when needed on commercially reasonable terms or at all, or that our actual cash requirements will not be greater than anticipated. We expect to also continue to seek to finance our operations through other sources, including out-licensing arrangements for the development and commercialization of our therapeutic candidates or other partnerships or joint ventures, as well as grants from government agencies and foundations. If we are unable to obtain future financing through the methods we describe above or through other means, we may be unable to complete our business objectives and may be unable to continue operations, which would have a material adverse effect on our business and financial condition.

We may be unable to make payments due under our secured loan agreement.

In October 2018, we entered into a $10 million loan agreement with Kreos Capital V (Expert Fund) L.P., or Kreos Capital. As security for the loan, Kreos Capital received a first-priority secured interest in all of our assets, including intellectual property. The loan had a 12-month interest-only period, which concluded in September 2019, followed by a 36-month repayment period beginning in October 2019. Borrowings under the loan bear interest at a fixed rate of 9.5% per annum.

Our ability to make the scheduled payments under the loan agreement or to refinance our debt obligations with Kreos Capital depends on numerous factors including, but not limited to, the amount of our cash reserves, our capital requirements and our ability to raise additional capital. We may be unable to maintain a level of cash reserves sufficient to permit us to pay the principal and accrued interest on the loan. If our cash reserves, cash flows and capital resources are insufficient to fund our debt obligations to Kreos Capital, we may be required to seek additional capital, restructure or refinance our indebtedness, or delay or abandon our research and development projects or other capital expenditures, which could have a material adverse effect on our business, financial condition, prospects or results of operations. There is no assurance that we would be able to take any of such actions, or that such actions would permit us meet our scheduled debt obligations under the Kreos Capital loan agreement.

Risks Related to Our Business and Regulatory Matters

If we or our licensees are unable to obtain U.S. and/or foreign regulatory approval for our therapeutic candidates, we will be unable to commercialize our therapeutic candidates.

To date, only one of our products, BL-5010, a legacy asset for the treatment of benign skin lesions, has been approved for marketing and sale. Currently, we have two clinical-stage therapeutic candidates in development: motixafortide (formerly referred to as BL-8040), a novel peptide for the treatment of stem cell mobilization, solid tumors and hematological malignancies, and AGI-134, an immuno-oncology agent in development for solid tumors. Our therapeutic candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization of drugs and devices. We are preparing to submit a New Drug Application, or NDA, for our lead therapeutic candidate, motixafortide, as a novel stem-cell mobilization agent for autologous bone marrow transplantation in multiple myeloma patients, which we expect to submit in mid-2022.Although we held a positive pre-NDA with the US Food and Drug Administration, or FDA, in which it agreed that our proposed data package is sufficient to support an NDA submission, we may not obtain marketing approval of motixafortide for stem cell mobilization from the FDA or for any other of our therapeutic candidates in a timely manner or at all. In the United States, we are required to submit NDA to obtain FDA approval before marketing motixafortide or any of our therapeutic candidates. An NDA must include extensive preclinical and clinical data and supporting information to establish the therapeutic candidate's safety, purity and potency, or efficacy, for each desired indication. The NDA must also include significant information regarding the product's pharmacology, toxicology, chemistry, manufacture and manufacturing controls. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. Upon submission of an NDA, the FDA must make an initial determination that the application is sufficiently complete to accept the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA, or ultimately be approved. If our planned application for motixafortide for stem cell mobilization is not accepted for review or approval, the FDA may require that we conduct additional clinical or preclinical trials, or take other actions before it will reconsider our application. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA may not consider any additional information to be complete or sufficient to support approval.

In addition, in connection with the clinical trials for motixafortide and AGI-134 and other therapeutic candidates that we may seek to develop in the future, either on our own or through out-licensing or co-development arrangements, we face the risk that:

- a therapeutic candidate or medical device may not prove safe or efficacious;
- 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 U.S. Food and Drug Administration, or FDA, or other regulatory authorities; and
- the results will justify 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.

Any delay in obtaining, or the failure to obtain, required regulatory approvals will materially and adversely affect our ability to generate future revenues from a particular therapeutic candidate. Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product or may impose restrictive conditions of use, including cautionary information, thereby limiting the size of the market for the product. We and our licensees, as applicable, also are, and will be, subject to numerous foreign regulatory requirements that govern the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all the risks associated with the FDA approval process that we describe above, as well as risks attributable to the satisfaction of foreign requirements. Approval by the FDA does not ensure approval by regulatory authorities outside the United States. Foreign jurisdictions may have different approval processes than those required by the FDA and may impose additional testing requirements for our therapeutic candidates.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including FDA approval. Clinical trials are expensive and complex, can take many years and have uncertain outcomes. We cannot necessarily predict whether we or our licensees will encounter problems with any of the completed, ongoing or planned clinical trials that will cause us, our licensees or regulatory authorities to delay or suspend clinical trials, or to delay the analysis of data from completed or ongoing clinical trials. In addition, because some of our clinical trials are investigator-initiated studies (i.e., we are not the study sponsor), we may have less control over these studies. We estimate that clinical trials of certain of our advanced therapeutic candidates will continue for several years, but they may take significantly longer to complete. Failure can occur at any stage of the testing, and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates, including, but not limited to:

- delays in securing clinical investigators or trial sites for the clinical trials;
- delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial;

- slower-than-anticipated patient recruitment and enrollment;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;
- uncertain dosing issues;
- an inability to monitor patients adequately during or after treatment; and
- problems with investigator or patient compliance with the trial protocols.

A number of companies in the pharmaceutical, medical device 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 clinical trials. Despite the results reported in earlier clinical trials for our therapeutic candidates, we do not know whether any Phase 3 or other clinical trials we or our licensees may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our therapeutic candidates. If later-stage 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.

Even if we obtain regulatory approvals, our therapeutic candidates will be subject to ongoing regulatory review and if we fail to comply with continuing U.S. and applicable foreign regulations, we could lose those approvals and our business would be seriously harmed.

Even if products we or our licensees develop receive regulatory approval or clearance, we or our licensees, as applicable, will be subject to ongoing reporting obligations, and the products and the manufacturing operations will be subject to continuing regulatory review, including FDA inspections. The outcome of this ongoing review may result in the withdrawal of a product from the market, the interruption of the manufacturing operations and/or the imposition of labeling and/or marketing limitations. Since many more patients are exposed to drugs and medical devices following their marketing approval, serious but infrequent adverse reactions that were not observed in clinical trials may be observed during the commercial marketing of the product. In addition, the manufacturer and the manufacturing facilities we or our licensees, as applicable, will use to produce any therapeutic candidate will be subject to periodic review and inspection by the FDA and other, similar foreign regulators. Later discovery of previously unknown problems with any product, manufacturer or manufacturing process, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on such product, manufacturer or manufacturing process;
- warning letters from the FDA or other regulatory authorities;
- withdrawal of the product from the market;
- suspension or withdrawal of regulatory approvals;
- refusal to approve pending applications or supplements to approved applications that we or our licensees submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our products;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; or
- adverse publicity.

If we, or our licensees, suppliers, third-party contractors, partners 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 licensees may lose marketing approval for any of our products, if any of our therapeutic products are approved, resulting in decreased or lost revenue from milestones, product sales or royalties.

We generally rely on third parties to conduct our preclinical studies and clinical trials and to provide other services, and those third parties may not perform satisfactorily, including by failing to meet established deadlines for the completion of such services.

We do not have the ability to conduct certain preclinical studies and clinical trials independently for our therapeutic candidates, and we rely on third parties, such as contract laboratories, contract research organizations, medical institutions and clinical investigators to conduct these studies and clinical trials. Our reliance on these third parties limits our control over these activities. The third-party contractors may not assign as great a priority to our clinical development programs or pursue them as diligently as we would if we were undertaking such programs directly. Accordingly, these third-party contractors may not complete activities on schedule, or may not conduct the studies or our clinical trials in accordance with regulatory requirements or with our trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if their performance is substandard, we may be required to replace them or add more sites to the studies. Although we believe that there are a number of other third-party contractors that we could engage to continue these activities, replacement of these third parties will result in delays and/or additional costs. As a result, our efforts to obtain regulatory approvals for, and to commercialize, our therapeutic candidates may be delayed. The third-party contractors may also have relationships with other commercial entities, some of whom may compete with us. If the third-party contractors assist our competitors, our competitive position may be harmed.

In addition, our ability to bring future products to market depends on the quality and integrity of 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. The failure of these third parties to carry out their obligations would materially adversely affect our ability to develop and market new products and implement our strategies.

We generally depend on out-licensing arrangements for late-stage development, marketing and commercialization of our therapeutic candidates.

We generally depend on out-licensing arrangements for late-stage development, marketing and commercialization of our therapeutic candidates. We have limited experience in late-stage development, marketing and commercializing therapeutic candidates. Dependence on out-licensing arrangements subjects us to a number of risks, including the risk that:

- we have limited control over the amount and timing of resources that our licensees devote to our therapeutic candidates;
- our licensees may experience financial difficulties;
- our licensees may fail to secure adequate commercial supplies of our therapeutic candidates upon marketing approval, if at all;
- our future revenues depend heavily on the efforts of our licensees;
- business combinations or significant changes in a licensee's business strategy may adversely affect the licensee's willingness or ability to complete its obligations under any arrangement with us;
- a licensee could move forward with a competing therapeutic candidate developed either independently or in collaboration with others, including our competitors; and
- out-licensing arrangements are often terminated or allowed to expire, which would delay the development and may increase the development costs of our therapeutic candidates.

If we or any of our licensees breach or terminate their agreements with us, or if any of our licensees otherwise fail to conduct their development and commercialization activities in a timely manner or there is a dispute about their obligations, we may need to seek other licensees, or we may have to develop our own internal sales and marketing capability for our therapeutic candidates. Our dependence on our licensees' experience and the rights of our licensees will limit our flexibility in considering alternative out-licensing arrangements for our therapeutic candidates. Any failure to successfully develop these arrangements or failure by our licensees to successfully develop or commercialize any of our therapeutic candidates in a competitive and timely manner will have a material adverse effect on the commercialization of our therapeutic candidates.

We depend on our ability to identify and in-license technologies and therapeutic candidates.

We employ a number of methods to identify therapeutic candidates that we believe are likely to achieve commercial success. In certain instances, disease-specific third-party advisors evaluate therapeutic candidates as we deem necessary. However, there can be no assurance that our internal research efforts or our screening system will accurately or consistently select among various therapeutic candidates those that have the highest likelihood to achieve, and that ultimately achieve, commercial success. As a result, we may spend substantial resources developing therapeutic candidates that will not achieve commercial success, and we may not advance those therapeutic candidates with the greatest potential for commercial success.

An important element of our strategy is maintaining relationships with universities, medical institutions and biotechnology companies in order to in-license potential therapeutic candidates. We may not be able to maintain relationships with these entities, and they may elect not to enter into in-licensing agreements with us or to terminate existing agreements. The existence of global companies with significantly greater resources than we have may increase the competition with respect to the in-licensing of promising therapeutic candidates. We may not be able to acquire licenses on commercially reasonable terms or at all. Failure to license or otherwise acquire necessary technologies could materially and adversely affect our business, financial condition and results of operations.

If we cannot meet requirements under our in-license agreements, we could lose the rights to our therapeutic candidates, which could have a material adverse effect on our business.

We depend on in-licensing agreements with third parties to maintain the intellectual property rights to our therapeutic candidates. We have in-licensed rights from Biokine Therapeutics Ltd., or Biokine, with respect to our motixafortide therapeutic candidate; from the University of Massachusetts and from Kode Biotech Limited, or Kode Biotech, with respect to our AGI-134 therapeutic candidate; and from Innovative Pharmaceutical Concepts, Inc., or IPC, with respect to our BL-5010 therapeutic candidate. See "Item 4. Information on the Company — Business Overview — In-Licensing Agreements." Our in-license agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these agreements. The royalty rates and revenue sharing payments vary from case to case but range from 20% to 29.5% of the consideration we receive from sublicensing the applicable therapeutic candidate and a substantially lower percentage (generally less than 5%) if we elect to commercialize the subject therapeutic candidate independently. Due to the relatively advanced stage of development of the compound licensed from Biokine, our license agreement with Biokine provides for royalty payments of 10% of net sales, subject to certain limitations, should we independently sell products. These in-license agreements last either throughout the life of the patents that are the subject of the agreements, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our in-license agreements in a timely manner, we could lose the rights to our proprietary technology, which could have a material adverse effect on our business, financial condition and results of operations.

If we do not meet the requirements under our agreement with the Agalimmune selling shareholders, we could lose the rights to the therapeutic candidates in Agalimmune's pipeline, including, but not limited to, AGI-134.

In March 2017, we acquired substantially all the outstanding shares of Agalimmune Ltd., or Agalimmune, a privately held company incorporated in the United Kingdom. In conjunction with the acquisition, we entered into a development agreement with Agalimmune and its selling shareholders, or the Agalimmune Development Agreement, which, among other things, grants us an option to purchase any remaining Agalimmune shares. If we do not exercise this option within a certain period of time after achieving certain milestones or we commit a material breach of the Agalimmune Development Agreement, the selling shareholders have a reversionary option to acquire all the Agalimmune shares we hold for nominal consideration. If the exercise of this reversionary option is completed and our development work subsequently generates revenues for Agalimmune, we will only be entitled to a percentage of Agalimmune's net proceeds, until such time as we have recouped the expenses we incurred in connection with the Agalimmune Development Agreement. Completion of the exercise of the reversionary option would result in the loss of our rights in the proprietary technology held by Agalimmune, which could have a material adverse effect on our business, financial condition and results of operations.

We seek to partner with third-party collaborators with respect to the development and commercialization of motixafortide, and we may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.

Our business strategy relies in part on partnering with pharmaceutical companies to complement our internal development efforts. We will be competing with many other companies as we seek partners for motixafortide and for any other therapeutic candidate and we may not be able to compete successfully against those companies. If we are not able to enter into collaboration arrangements for motixafortide and for any other therapeutic candidate, we may be required to undertake and fund further development, clinical trials, manufacturing and commercialization activities solely at our own expense and risk. If we are unable to finance and/or successfully execute those expensive activities, or we delay such activities due to capital availability, our business could be materially and adversely affected, and potential future product launch could be materially delayed, be less successful, or we may be forced to discontinue clinical development of these product candidates. Furthermore, if we are unable to enter into a commercial agreement for the development and commercialization of motixafortide and for any other therapeutic candidate, then this could have a material adverse effect on our business, financial condition or results of operations.

The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- a collaboration partner may shift its priorities and resources away from our therapeutic candidates due to a change in business strategies, or a merger, acquisition, sale or downsizing;
- a collaboration partner may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaboration partner may cease development in therapeutic areas which are the subject of our strategic collaboration;
- a collaboration partner may not devote sufficient capital or resources towards our therapeutic candidates;
- a collaboration partner may change the success criteria for a therapeutic candidate thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner could develop a product that competes, either directly or indirectly, with our therapeutic candidate;

- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a partner may exercise a contractual right to terminate a strategic alliance;
- a dispute may arise between us and a partner concerning the research, development or commercialization of a therapeutic candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and
- a partner may use our products or technology in such a way as to invite litigation from a third party.

Any collaborative partners we enter into agreements with in the future may shift their priorities and resources away from our therapeutic candidates or seek to renegotiate or terminate their relationships with us. If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

We have no experience selling, marketing or distributing products and no internal capability to do so.

We currently have no sales, marketing or distribution capabilities and no experience in building a sales force or distribution capabilities. To be able to commercialize any of our therapeutic candidates upon approval, if at all, we must either develop internal sales, marketing and distribution capabilities, which will be expensive and time-consuming, or enter into out-licensing arrangements with third parties to perform these services.

While we continue to seek a third party collaborator to commercialize motixafortide, we are also undertaking selected pre-commercialization activities necessary for an NDA submission, and for a timely launch, if approved by the FDA, with a view to obtaining potential FDA approval and potentially launching sales in 2023. There are risks involved with establishing our own sales, marketing and distribution capabilities. If we decide to market any of therapeutic candidates on our own, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Factors that may inhibit our efforts to commercialize our products directly and without strategic partners include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our therapeutic candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

We may not be successful in recruiting the sales and marketing personnel necessary to sell any of our therapeutic candidates upon approval, if at all, and, even if we do build a sales force, we may not be successful in marketing our therapeutic candidates, which would have a material adverse effect on our business, financial condition and results of operations.

If we are unable to establish our own sales, marketing and distribution capabilities or enter into successful arrangements with third parties to perform these services, any future product revenues and our profitability, may be materially adversely affected.

Our business is subject to risks arising from a widespread outbreak of an illness or any other communicable disease, or any other public health crisis, such as the COVID-19 pandemic, which has impacted and could continue to impact our business.

The novel coronavirus outbreak, or COVID-19, has affected segments of the global economy and may materially affect our operations, including potentially interrupting our supply chain, clinical trial and commercialization activities. COVID-19 originated in Wuhan, China, in December 2019 and was declared a pandemic by the WHO in March 2020. Due to clinical operating issues associated with the COVID-19 pandemic, we previously temporarily suspended enrollment to the phase 1/2a study we are currently conducting for AGI-134, our second lead compound. The uncertainty surrounding the severity and continued spread of the coronavirus may result in a period of prolonged business disruption. COVID-19 may continue to impact our future operations, including potential interruptions to supply chains, clinical trials, commercialization activities and regulatory reviews and approvals. COVID-19 may also affect our employees and employees and operations at suppliers that may result in delays or disruptions in supply. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our shares. Additionally, if the COVID-19 pandemic has a significant impact on our business and financial results for an extended period of time, our liquidity and cash resources could be negatively impacted. Capital and credit markets have been disrupted by the crisis and exchanges have experienced increased volatility. As a result, access to additional financing may be challenging and is largely dependent upon evolving market conditions and other factors. We have taken precautionary measures, including, for example, a Company-wide salary reduction related to the COVID-19 pandemic carried out in the second and third quarters of 2020, and may take additional measures, intended to minimize the risk of COVID-19 to our employees and operations. The extent of the impact of COVID-19 on our operational and financial performance, including our ability to execute our business strategies in the expected time frame or at all, will depend on future developments, such as the duration and spread of the COVID-19 pandemic and related restrictions and implications and the effectiveness of actions taken to contain and treat the disease, all of which are uncertain and cannot be predicted. The impact of the COVID-19 pandemic may also have the effect of heightening many of the other risks described in the "Risk Factors" section of this Annual Report on Form 20-F.

Modifications to our therapeutic candidates, or to any other therapeutic candidates that we may develop in the future, may require new regulatory clearances or approvals or may require us or our licensees, as applicable, to recall or cease marketing these therapeutic candidates until clearances are obtained.

Modifications to our therapeutic candidates, after they have been approved for marketing, if at all, or to any other pharmaceutical product or medical device that we may develop in the future, may require new regulatory clearance or approvals, and, if necessitated by a problem with a marketed product, may result in the recall or suspension of marketing of the previously approved and marketed product until clearances or approvals of the modified product are obtained. The FDA requires pharmaceutical products and device manufacturers to initially make and document a determination of whether a modification requires a new approval, supplement or clearance. A manufacturer may determine in conformity with applicable regulations and guidelines that a modification may be implemented without pre-clearance by the FDA; however, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. If the FDA requires new clearances or approvals of any pharmaceutical product or medical device for which we or our licensees receive marketing approval, if any, we or our licensees may be required to recall such product and to stop marketing the product as modified, which could require us or our licensees to redesign the product and will have a material adverse effect on our business, financial condition and results of operations. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect the safety or efficacy of the device, would constitute a major change in its intended use, or otherwise requires pre-clearance, the modification may not be implemented without the requisite clearance. We or our licensees may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. For those products sold in the European Union, or EU, we or our licensees, as applicable, must notify the applicable EU Notified Body, an organization appointed by a member state of the EU either for the approval and monitoring of a manufacturer's quality assurance system or for direct product inspection, if significant changes are made to the product or if there are substantial changes to the quality assurance systems affecting the product. Delays in obtaining required future clearances or approvals would materially and adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would have a material adverse effect on our business, financial condition and results of operations.

If our competitors develop and market products that are more effective, safer or less expensive than our current or future therapeutic candidates, our prospects will be negatively impacted.

The life sciences 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 for which we are currently developing therapeutic candidates or for which we may develop therapeutic candidates in the future. Specifically, we are aware of other companies that currently market and/or are in the process of developing products that address stem cell mobilization, acute myeloid leukemia, or AML, solid malignancies and skin lesions.

An important element of our strategy for identifying future products is maintaining relationships with universities, medical institutions and biotechnology companies in order to in-license potential therapeutic candidates, and we compete with respect to this in-licensing with a number of global pharmaceutical companies. The presence of these global companies with significantly greater resources than we have may increase the competition with respect to the in-licensing of promising therapeutic candidates. Our failure to license or otherwise acquire necessary technologies could materially and adversely affect our business, financial condition and results of operations.

Our contract manufacturers are, and will be, subject to FDA and other comparable agency regulations.

Our contract manufacturers are, and will be, required to adhere to FDA regulations setting forth current good manufacturing practices, or GMP, for drugs and Quality System Regulations, or QSR, for devices. These regulations cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our therapeutic candidates. Our manufacturers may not be able to comply with applicable regulations. Our manufacturers are and will be subject to unannounced inspections by the FDA, state regulators and similar regulators outside the United States. The failure of our third-party manufacturers to comply with applicable regulations 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 candidates or products, 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 business could suffer if we are unable to attract and retain key employees.

Our success depends upon the continued service and performance of our senior management and other key personnel. The loss of the services of these personnel could delay or prevent the successful completion of our planned 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. Although we have entered into employment agreements with all of the members of our senior management team, members of our senior management team may resign at any time. High demand exists for senior management and other key personnel in the pharmaceutical industry. There can be no assurance that we will be able to continue to retain and attract such personnel.

Our growth and success also depend on our ability to attract and retain additional highly qualified scientific, technical, sales, managerial and finance personnel. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers. In addition, if we elect to independently commercialize any therapeutic candidate, we will need to expand our marketing and sales capabilities. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel. If we cannot attract and retain sufficiently qualified technical employees on acceptable terms, we may not be able to develop and commercialize competitive products. Further, any failure to effectively integrate new personnel could prevent us from successfully growing our company.

We rely upon third-party manufacturers to produce therapeutic supplies for the clinical trials, and commercialization, of our therapeutic candidates. If we manufacture any of our therapeutic candidates in the future, we will be required to incur significant costs and devote significant efforts to establish and maintain manufacturing capabilities.

We do not currently have laboratories that are compliant with cGMP and therefore cannot independently manufacture drug products for our current clinical trials. We rely on third-party manufacturers to produce the therapeutic supplies that will enable us to perform clinical trials and, if we choose to do so, commercialize therapeutic candidates ourselves. We have limited personnel with experience in drug or medical device manufacturing and we lack the resources and capabilities to manufacture any of our therapeutic candidates on a commercial scale. The manufacture of pharmaceutical products and medical devices requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products and medical devices often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields and quality control, including stability of the therapeutic candidate.

We do not currently have any long-term agreements with third-party manufacturers that guarantee the supply of any of our therapeutic candidates. When we require additional supplies of our therapeutic candidates to complete our clinical trials or if we elect to commercialize our products independently, we may be unable to enter into agreements for clinical or commercial supply, as applicable, with third-party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements, it is likely that the manufacturers of each therapeutic candidate will be single-source suppliers to us for a significant period of time.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured therapeutic candidates ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
- impact on our reputation in the marketplace if manufacturers of our products, once commercialized, fail to meet customer demands;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

The failure of any of our contract manufacturers to maintain high manufacturing standards could result in injury or death of clinical trial participants or patients being treated with our products. Such failure could also result in product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems, which would have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Industry

Even if our therapeutic candidates receive regulatory approval or do not require regulatory approval, they may not become commercially viable products.

Even if our therapeutic candidates are approved for commercialization, they may not become commercially viable products. For example, if we or our licensees receive regulatory approval to market a product, approval may be subject to limitations on the indicated uses or subject to labelling or marketing restrictions, which could materially and adversely affect the marketability and profitability of the product. In addition, a new product may appear promising at an early stage of development or after 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;
- low market acceptance by physicians, healthcare payors, 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 payors;
- infringement on proprietary rights of others for which we or our licensees have not received licenses;
- incompatibility with other therapeutic products;
- other potential advantages of alternative treatment methods;
- ineffective marketing and distribution support;
- significant changes in pricing due to pressure from public opinion, non-governmental organizations or governmental authorities;
- lack of cost-effectiveness; or
- timing of market introduction of competitive products.

If we are unable to develop commercially viable products, either on our own or through licensees, our business, results of operations and financial condition will be materially and adversely affected.

Healthcare reforms and related reductions in pharmaceutical pricing, reimbursement and coverage by governmental authorities and third-party payors may adversely affect our business.

The continuing increase in expenditures for healthcare has been the subject of considerable government attention, particularly as public resources have been stretched by financial and economic crises in the United States, Western Europe and elsewhere. Both private health insurance funds and government health authorities continue to seek ways to reduce or contain healthcare costs, including by reducing or eliminating coverage for certain products and lowering reimbursement levels. In many countries and regions, including the United States, Western Europe, Israel, Russia, certain countries in Central and Eastern Europe and several countries in Latin America, pharmaceutical prices are subject to new government policies designed to reduce healthcare costs. These changes frequently adversely affect pricing and profitability and may cause delays in market entry. We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our approved products, if any of our therapeutic products are approved.

Significant developments that may adversely affect pricing in the United States include (i) the enactment of federal healthcare reform laws and regulations, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the Patient Protection and Affordable Care Act of 2010, or PPACA, and (ii) trends in the practices of managed care groups and institutional and governmental purchasers, including the impact of consolidation of our customers. Changes to the healthcare system enacted as part of healthcare reform in the United States, as well as the increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, may result in increased pricing pressure by influencing, for instance, the reimbursement policies of third-party payors. Healthcare reform legislation has increased the number of patients who would have insurance coverage for our approved products, if any of our therapeutic products are approved, but provisions such as the assessment of a branded pharmaceutical manufacturer fee and an increase in the amount of the rebates that manufacturers pay for coverage of their drugs by Medicaid programs may have an adverse effect on us. It is uncertain how current and future reforms in these areas will influence the future of our business operations and financial condition, as federal, state and foreign governmental authorities are likely to continue efforts to control the price of drugs and reduce overall healthcare costs. These efforts could have an adverse impact on our ability to market products and generate revenues in the United States and foreign countries.

If third-party payors do not adequately reimburse customers for any of our therapeutic candidates that are approved for marketing, 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 reimbursement for the use of our approved candidates, if any, from governmental or other third-party payors, both in the United States and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that the use of an approved product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each government or other third-party payor is a time-consuming and costly process that could require us or our licensees to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or comparable foreign regulatory authorities. Reimbursement rates may vary according to the use of the product and the clinical setting in which it 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 and/or imperfections in Medicare, Medicaid or other data used to calculate these rates.

Regardless of the impact of the PPACA on us, the U.S. government, other governments and commercial payors have shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could cause significant pressure on the pricing of healthcare products and services, including those biopharmaceuticals currently being developed by us or our licensees, in the United States and internationally, as well as the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors to contain or reduce healthcare costs may compromise our ability to set prices at commercially attractive levels for our products that we may develop, which in turn could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our products, if approved. Changes in healthcare policy, such as the creation of broad limits for diagnostic products, could substantially diminish the sale of or inhibit the utilization of diagnostic tests, increase costs, divert management's attention and adversely affect our ability to generate revenues and achieve consistent profitability. This could materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products, if approved.

Further, the Centers for Medicare and Medicaid Services, or CMS, frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payors may have sufficient market power to demand significant price reductions.

Our business has a substantial risk of clinical trial and product liability claims. If we are unable to obtain and maintain appropriate levels of insurance, a claim could adversely affect our business.

Our business exposes us to significant potential clinical trial and product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Claims could be made against us based on the use of our therapeutic candidates in clinical trials and in marketed products. We currently carry life science liability insurance covering general liability with an annual coverage amount of $30.0 million per occurrence and product liability and clinical trials coverage with an annual coverage amount of $30.0 million each claim and in the aggregate. The annual aggregate as well as the maximum indemnity for a single occurrence, claim or circumstances under this insurance is $30.0 million. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or to obtain additional or sufficient insurance at a reasonable cost to protect against losses that could have a material adverse effect on us. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as damages awards beyond the coverage of our insurance policies resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any claims, we might be required to direct significant financial and managerial resources to such defense, and adverse publicity is likely to result.

Significant disruptions of our information technology systems or breaches of our data security could adversely affect our business.

A significant invasion, interruption, destruction or breakdown of our information technology systems and/or infrastructure by persons with authorized or unauthorized access could negatively impact our business and operations. We could experience business interruption, information theft and/or reputational damage from cyber-attacks or cyber-intrusions over the Internet, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, and attachments to emails. Any of the foregoing may compromise our systems and lead to data leakage either internally or at our third-party providers. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or 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. Our systems have been, and are expected to continue to be, the target of malware and other cyber-attacks. Although we have invested in measures to reduce these risks, we cannot assure you that these measures will be successful in preventing compromise and/or disruption of our information technology systems and related data.

We deal with hazardous materials and must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do business.

Our activities and those of our third-party manufacturers on our behalf involve the controlled storage, use and disposal of hazardous materials, including microbial agents, corrosive, explosive and flammable chemicals, as well as cytotoxic, biologic, radio-labeled and other hazardous compounds. We and our manufacturers are subject to U.S. federal, state, local, Israeli and other foreign laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In addition, if we develop a manufacturing capacity, we may incur substantial costs to comply with environmental regulations and would be subject to the risk of accidental contamination or injury from the use of hazardous materials in our manufacturing process.

In the event of an accident, government authorities may curtail our use of these materials and interrupt our business operations. In addition, we could be liable for any civil damages that result, which may exceed our financial resources and may seriously harm our business. Although our Israeli insurance program covers certain unforeseen sudden pollutions, we do not maintain a separate insurance policy for any of the foregoing types of risks. In addition, although the general liability section of our life sciences policy covers certain unforeseen, sudden environmental issues, pollution in the United States and Canada is excluded from the policy. In the event of environmental discharge or contamination or an accident, we may be held liable for any resulting damages, and any liability could exceed our resources. In addition, we may be subject to liability and may be required to comply with new or existing environmental laws regulating pharmaceuticals or other medical products in the environment.

Risks Related to Intellectual Property

Our access to most of the intellectual property associated with our therapeutic candidates results from in-license agreements with biotechnology companies and a university, the termination of which would prevent us from commercializing the associated therapeutic candidates.

We do not conduct our own initial research with respect to the identification of our therapeutic candidates. Instead, we rely upon research and development work conducted by third parties as the primary source of our therapeutic candidates. As such, we have obtained our rights to our therapeutic candidates through in-license agreements entered into with biotechnology companies and a university that invent and own the intellectual property underlying our candidates. There is no assurance that such in-licenses or rights will not be terminated or expire due to a material breach of the agreements, such as a failure on our part to achieve certain progress milestones set forth in the terms of the in-licenses or due to the loss of the rights to the underlying intellectual property by any of our licensors. There is no assurance that we will be able to renew or renegotiate an in-licensing agreement on acceptable terms if and when the agreement terminates. We cannot guarantee that any in-license is enforceable or will not be terminated or converted into a non-exclusive license in the future. The termination of any in-license or our inability to enforce our rights under any in-license would materially and adversely affect our ability to commercialize certain of our therapeutic candidates.

We currently have in-licensing agreements relating to our therapeutic candidates that are in development or being commercialized. In 2012, we in-licensed the rights to motixafortide under a license agreement from Biokine. Under the license agreement for motixafortide, we are obligated to make commercially reasonable, good faith efforts to sublicense or commercialize motixafortide for fair consideration. Agalimmune in-licensed rights to AGI-134 under a license from the University of Massachusetts in 2013 and under a license from Kode Biotech in 2015. Under each of those license agreements, Agalimmune is obligated to use diligent efforts or cause its affiliates and sublicensees to use diligent efforts to develop the respective licensed technology and introduce licensed products into the commercial market. In 2007, we in-licensed the rights to BL-5010 under a license agreement with IPC. Under the BL-5010 license agreement, we are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan, including meeting certain specified diligence goals.

Each of the foregoing in-licensing agreements, or the obligation to pay royalties thereunder, will generally remain in effect until the expiration, under the applicable agreement, of all the licensing, royalty and sublicense revenue obligations to the applicable licensors, determined on a product-by-product and country-by-country basis. We may terminate the motixafortide in-licensing agreement upon 90 days' prior written notice to Biokine. Agalimmune may terminate each of the in-licensing agreements with University of Massachusetts and Kode Biotech relating to AGI-134, on 90 days' notice. We may terminate the BL-5010 in-licensing agreement upon 30 days' prior written notice to IPC.

Any party to any of the foregoing in-licensing agreements may terminate the respective agreement for material breach by the other party if the breaching party is unable to cure the breach within an agreed-upon period, generally 30 days to 90 days, after receiving written notice of the breach from the non-breaching party.

Patent protection for our products is important and uncertain.

Our success depends, in part, on our ability, and the ability of our licensees and licensors 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., European, Israeli and other patent applications related to our proprietary products, technologies, inventions and improvements that may be important to the continuing development of our therapeutic candidates. As of March 15, 2022, we owned or exclusively licensed for uses within our field of business 32 patent families that collectively contain over 111 issued patents, two allowed patent applications and over 91 pending patent applications relating to our therapeutic candidates.

Because the patent position of biopharmaceutical companies involves complex legal and factual questions, we cannot predict the validity and enforceability of patents with certainty. Our issued patents and the issued patents of our licensees or licensors may not provide us with any competitive advantages or may be held invalid or unenforceable as a result of legal challenges by third parties. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those 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 against competitors with similar technology. 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 do have will only extend to those countries in which we have 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 United States. For example, the patent laws of China and India are relatively new and are not as developed as are older, more established patent laws of other countries. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that do not respect our 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.

Our technology may infringe the rights of third parties. The nature of claims contained in unpublished patent filings around the world is unknown to us and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. Any infringement by us of the proprietary rights of third parties may have a material adverse effect on our business, financial condition and results of operations.

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.

We rely on a combination of patents, trade secrets, know-how, technology, trademarks and regulatory exclusivity to maintain our competitive position. We generally try to protect trade secrets, know-how and technology by entering into confidentiality or non-disclosure agreements with parties that have access to it, such as our licensees, employees, contractors and consultants. We also enter into agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees, advisors, research collaborators, contractors and consultants while we employ or engage them. However, these agreements can be difficult and costly to enforce or may not provide adequate remedies. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

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.

Legal proceedings or third-party claims of intellectual property infringement may require us to spend substantial time and money and could prevent us from developing or commercializing products.

The development, manufacture, use, offer for sale, sale or importation of our therapeutic candidates may infringe on the claims of third-party patents. A party might file an infringement action against us. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of a patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time. Consequently, we are unable to guarantee that we will be able to manufacture, use, offer for sale, sell or import our therapeutic candidates in the event of an infringement action. At present, we are not aware of pending or threatened patent infringement actions against us.

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 claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses could harm our business significantly. At present, we have not received any written demands from third parties that we take a license under their patents nor have we received any notice form a third party accusing us of patent infringement.

Our license agreements with our licensees contain, and any contract that we enter into with licensees in the future will likely contain, indemnity provisions that obligate us to indemnify the licensee against any losses arising from infringement of third-party intellectual property rights. In addition, our in-license agreements contain provisions that obligate us to indemnify the licensors against any damages arising from the development, manufacture and use of products developed on the basis of the in-licensed intellectual property.

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, including interference or re-examination proceedings filed with the U.S. Patent and Trademark Office or opposition proceedings in other foreign patent offices regarding intellectual property rights with respect to our products and technology, as well as other disputes regarding intellectual property rights with licensees, licensors or others with whom we have contractual or other business relationships. Post-issuance oppositions are not uncommon and we, our licensee or our licensor 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.

We may be subject to damages resulting from claims that we or our employees or contractors have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees and contractors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or any employee or contractor has inadvertently or otherwise used or disclosed trade secrets or other proprietary information of his or her former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain therapeutic candidates, which could severely harm our business, financial condition and results of operations. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to our Ordinary Shares and ADSs

We may be a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for our taxable year ending December 31, 2022 or in any subsequent year. There may be negative tax consequences for U.S. taxpayers that are holders of our ordinary shares or our ADSs if we are a PFIC.

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. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. We believe that we were a PFIC during certain prior taxable years, although we believe that we were not a PFIC for the year ended December 31, 2021. Although we have not determined whether we will be a PFIC for our taxable year ending December 31, 2022, or in any subsequent year, our operating results for any such years may cause us to be a PFIC. Because PFIC status is determined annually and is based on our income, assets and activities for the entire taxable year, it is not possible to determine with certainty whether we will be characterized as a PFIC for the 2022 taxable year until after the close of the year, and there can be no assurance that we will not be classified as a PFIC in any future year. If we are a PFIC for our taxable year ending December 31, 2022, or any subsequent year, and a U.S. Investor (as defined below) does not make an election to treat us as a "qualified electing fund," or QEF, or make a "mark-to-market" election, then "excess distributions" to a U.S. Investor, and any gain realized on the sale or other disposition of our ordinary shares or ADSs will be subject to special rules. Under these rules: (i) the excess distribution or gain would be allocated ratably over the U.S. Investor's holding period for the ordinary shares (or ADSs, as the case may be); (ii) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (iii) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the U.S. Internal Revenue Service, or the IRS, determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. Investor to make a timely QEF or mark-to-market election. U.S. Investors who hold our ordinary shares or ADSs during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. Investors who made a timely QEF or mark-to-market election. A U.S. Investor can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. A QEF election generally may not be revoked without the consent of the IRS. Upon request, we intend to annually furnish U.S. Investors with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. Investor) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC. See also "Item 10. Additional Information—E. Taxation—U.S. Federal Income Tax Considerations."

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. In February 2022, Russia launched a full-scale military invasion of Ukraine. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets. Additionally, Russia's prior annexation of Crimea, recent recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military interventions in Ukraine have led to sanctions and other penalties being levied by the United States, European Union and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so-called Donetsk People's Republic, and the so-called Luhansk People's Republic, including agreement to remove certain Russian financial institutions from the Society for Worldwide Interbank Financial Telecommunication (SWIFT) payment system. Additional potential sanctions and penalties have also been proposed and/or threatened. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Annual Report on Form 20-F.

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

The stock market in general and the market prices of our ordinary shares on the TASE and ADSs on Nasdaq, in particular, are subject to fluctuation, and changes in these prices may be unrelated to our operating performance. We expect that the market prices of our ordinary shares and ADSs will continue to be subject to wide fluctuations. The market price of our ordinary shares and ADSs are and will be subject to a number of factors, including:

- announcements of technological innovations or new products by us or others;
- announcements by us of significant acquisitions, strategic partnerships, in-licensing, out-licensing, joint ventures or capital commitments;
- expiration or terminations of licenses, research contracts or other collaboration agreements;
- public concern as to the safety of drugs we, our licensees or others develop;
- general market conditions;
- the volatility of market prices for shares of biotechnology companies generally;
- success of research and development projects;
- departure of key personnel;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares or ADSs are covered by analysts;
- statements about the Company made in the financial media or by bloggers on the Internet;
- statements made about drug pricing and other industry-related issues by government officials;
- changes in government regulations or patent decisions;
- developments by our licensees; and
- general market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our ordinary shares and ADSs, and result in substantial losses by our investors. See also Risk Factors—Risks Related to our Ordinary Shares and ADSs—"*We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine.*"

Additionally, market prices for securities of biotechnology and pharmaceutical companies historically have been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons unrelated to the operating performance of any one company. A significant outbreak of contagious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn. 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.

Our ordinary shares are traded on the TASE and our ADSs are listed on Nasdaq. Trading in our securities on these markets takes place in different currencies (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 United States and Israel). The trading prices of our securities on these two markets may differ due to these factors, the factors listed above, or 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.

Future sales of our ordinary shares or ADSs could reduce the market price of our ordinary shares and ADSs.

Substantial sales of our ordinary shares or ADSs, either on the TASE or on Nasdaq, may cause the market price of our ordinary shares or ADSs to decline. Sales by us or our securityholders of substantial amounts of our ordinary shares or ADSs, or the perception that these sales may occur in the future, could cause a reduction in the market price of our ordinary shares or ADSs.

As of March 15, 2022, as a result of previous financings, we had warrants outstanding (i) for the purchase of 63,837 ADSs at an exercise price of $14.10 per ADS, (ii) for the purchase of 1,866,667 ADSs at an exercise price of $11.25 per ADS, (iii) for the purchase of 2,175,524 ADSs at an exercise price of $2.25 per ADS, (iv) for the purchase of 120,537 ADSs at an exercise price of $2.185 per ADS and (vi) for the purchase of 718,750 ADSs at an exercise price of $3.00 per ADS.

On September 25, 2020, we entered into an offering agreement, or the Original HCW Offering Agreement, with HCW. Pursuant to Original HCW Offering Agreement, we were able to offer and sell, from time to time, at our option, up to $25.0 million of our ADSs through an “at-the-market” equity offering program under which HCW agreed to act as sales agent. From the effective date of the Original HCW Offering Agreement through September 3, 2021, we had sold an aggregate of 7,381,101 ADSs for an aggregate offering price of $24.5 million. On September 3, 2021, the Original HCW Offering Agreement was terminated.

On September 3, 2021, we entered into a new offering agreement, or the New HCW Offering Agreement, with HCW, pursuant to which we may offer and sell, at our option, up to $25.0 million of our ADSs through an “at-the-market” equity program under which HCW agreed to act as sales agent. As of March 15, 2022, we have sold 402,327 of our ADSs for total gross proceeds of approximately $1.1 million under the New HCW Offering Agreement.

As of March 15, 2022, in the framework of our Share Incentive Plan, there are outstanding stock options, restricted stock units and performance stock units (granted to directors, employees and consultants) for the purchase of 43.7 million ordinary shares with a weighted average exercise price of $0.21 per ordinary share.

The issuance of any additional ordinary shares, any additional ADSs, or any securities that are exercisable for or convertible into our ordinary shares or ADSs, may have an adverse effect on the market price of our ordinary shares and ADSs and will have a dilutive effect on our shareholders.

Raising additional capital by issuing securities may cause dilution to existing shareholders.

We may need to raise substantial future capital to continue to complete clinical development and commercialize our products and therapeutic candidates and to conduct the research and development and clinical and regulatory activities necessary to bring our therapeutic candidates to market. Our future capital requirements will depend on many factors, including:

- the failure to obtain regulatory approval or achieve commercial success of our therapeutic candidates;
- our success in effecting out-licensing arrangements with third parties;
- our success in establishing other out-licensing or co-development arrangements;
- the success of our licensees in selling products that utilize our technologies;
- the results of our preclinical studies and clinical trials for our earlier stage therapeutic candidates, and any decisions to initiate clinical trials if supported by the preclinical results;
- the costs, timing and outcome of regulatory review of our therapeutic candidates that progress to clinical trials;
- the costs of establishing or acquiring specialty sales, marketing and distribution capabilities, if any of our therapeutic candidates are approved, and we decide to commercialize them ourselves;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our issued patents and defending intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products or technologies and other strategic relationships; and
- the costs of financing unanticipated working capital requirements and responding to competitive pressures.

If we raise additional funds through licensing arrangements with third parties, we may have to relinquish valuable rights to our therapeutic candidates or grant licenses on terms that are not favorable to us. If we raise additional funds by issuing equity or convertible debt securities, we will reduce the percentage ownership of our then-existing shareholders, and these securities may have rights, preferences or privileges senior to those of our existing shareholders. See also "— Future sales of our ordinary shares or ADSs could reduce the market price of our ordinary shares and ADSs."

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of applicable SEC and Nasdaq requirements, which may result in less protection than is accorded to investors under rules applicable to 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 Listing Rules of the Nasdaq Stock Market, or the Nasdaq Rules, for U.S. domestic issuers. For instance, we may follow home country practice in Israel with regard to, among other things, composition of the board of directors, director nomination procedure, composition of the compensation committee, approval of compensation of officers, and quorum at shareholders' meetings. In addition, we will follow our home country law, instead of the Nasdaq 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. 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 Rules applicable to U.S. domestic issuers. See "Item 16G — Corporate Governance — Nasdaq Listing Rules and Home Country Practices."

In addition, as a foreign private issuer, we are exempt from the rules and regulations under the U.S. Securities Exchange Act of 1934, as amended, or 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.

Risks Related to our Operations in Israel

We conduct our operations in Israel and therefore our results may be adversely affected by political, economic and military instability in Israel and its region.

Our headquarters, our operations and some of our suppliers and third-party contractors are located in central Israel and our key employees, officers and most of our directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. 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. From time to time and most recently in May and June of 2021, Israel has been engaged in armed conflicts with Hamas, a militia group and political party operating in the Gaza Strip; These conflicts involved missile strikes against civilian targets in various parts of Israel, as well as civil insurrection of Palestinians in the West Bank, on the border with the Gaza Strip and in Israeli cities, and negatively affected business conditions in Israel. In addition, Israel faces threats from more distant neighbors, in particular Iran. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah (a Lebanese Islamist Shiite militia group and political party), and various rebel militia groups in Syria, as well as having a limited military presence in Syria. Additionally, Iran has threatened to attack Israel and may be developing nuclear weapons. These threats may escalate in the future to more violent events that may affect Israel and us. Among other things, this instability may affect the global economy and marketplace through changes in oil and gas prices. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. For example, any major escalation in hostilities in the region could result in a portion of our employees being called up to perform military duty for an extended period of time. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may 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 the agreements.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business. If the BDS Movement, the movement for boycotting, divesting and sanctioning Israel and Israeli institutions (including universities) and products become increasingly influential in the United States and Europe, this may also adversely affect our financial condition.

Due to a significant portion of our expenses and revenues being denominated in non-dollar currencies, our results of operations may be harmed by currency fluctuations.

Our reporting and functional currency is the dollar. However, we pay a significant portion of our expenses in NIS and in euro, and we expect this to continue. If the dollar weakens against the NIS or the euro in the future, there may be a negative impact on our results of operations. Although we expect our revenues from future licensing arrangements to be denominated primarily in dollars, we are exposed to the currency fluctuation risks relating to the recording of our revenues in currencies other than dollars. For example, if the euro strengthens against the dollar, our reported revenues in dollars may be lower than anticipated. From time to time, we engage in currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of the currencies mentioned above in relation to the dollar. These measures, however, may not adequately protect us from material adverse effects.

We have received Israeli government grants for certain research and development expenditures. The terms of these grants may require us to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. We may be required to pay penalties in addition to repayment of the grants.

Our research and development efforts were previously financed, in part, through grants that we received from the Israel Innovation Authority, or the IIA (formerly the Office of the Chief Scientist of Israel's Ministry of Economy and Industry, or the OCS). In addition, before we in-licensed motixafortide, Biokine had received funding for the project from the IIA, and as a condition to IIA consent to our in-licensing of motixafortide, we were required to agree to abide by any obligations resulting from such funding. We therefore must comply with the requirements of the Israeli Law for the Encouragement of Industrial Research, Development and Technological Innovation, 1984, and related regulations, as amended, or the Research Law, with respect to these projects. Through December 31, 2021, we received approximately $22.0 million in funding from the IIA and paid the IIA approximately $7.0 million in royalties under our approved programs. As of December 31, 2021, we have no contingent obligation to the IIA other than for motixafortide as agreed when we in-licensed the project. The contingent liability to the IIA assumed by us relating to this transaction (which liability has no relation to the funding actually received by us) amounts to $3.6 million as of December 31, 2021. We have a full right of offset for amounts payable to the IIA from payments that we may owe to Biokine in the future.

The transfer or licensing to third parties of know-how or technologies developed under the programs submitted to the IIA and derivatives thereof and as to which we or our licensors received grants, or manufacturing or rights to manufacture based on and/or incorporating such know-how to third parties, might require the consent of the IIA, and may require certain payments to the IIA. There is no assurance that we will be able to obtain such consent on terms acceptable to us, or at all. Although such restrictions do not apply to the export from Israel of our products developed with such know-how, without receipt of the aforementioned consent, such restrictions may prevent or limit us from engaging in transactions with our affiliates, customers or other third parties outside Israel, involving transfer or licensing of manufacturing rights or other know-how or assets that might otherwise be beneficial to us.

Provisions of Israeli law may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives the approval of at least 95% of the issued share capital (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer, except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer), and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, claim that the consideration for the acquisition of the shares did not reflect their fair market value and petition the court to alter the consideration for the acquisition accordingly (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights, and the acquirer or the company published all required information with respect to the tender offer prior to the date indicated for response to the tender offer).

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting 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 fulfilment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable, even if no actual disposition of the shares has occurred.

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

We have received Israeli government grants for certain research and development expenditures. The terms of these grants may require us to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. We may be required to pay penalties in addition to repayment of the grants. Such grants may be terminated or reduced in the future, which would increase our costs. See "Business — Government Regulation and Funding — Israeli Government Programs."

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

We are incorporated in Israel. All of our executive officers and the majority of our directors reside outside of the United States, and all of our assets and most of the assets of our executive officers and directors are located outside of the United States. Therefore, a judgment obtained against us or any of our executive officers and directors in the United States, including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel.

Your rights and responsibilities as a shareholder will be governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. companies.

We are incorporated under Israeli law. The rights and responsibilities of the holders of our ordinary shares are governed by our Articles of Association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders in typical U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith 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 interested party transactions requiring shareholder approval. In addition, a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in 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 liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal and commercial name is BioLineRx Ltd. We are a company limited by shares organized under the laws of the State of Israel. Our principal executive offices are located at 2 HaMa'ayan Street, Modi'in 7177871, Israel, and our telephone number is +972 (8) 642-9100.

We were founded in 2003 by leading institutions in the Israeli life sciences industry. We completed our initial public offering in Israel in February 2007 and our ordinary shares are traded on the TASE under the symbol "BLRX." In July 2011, we listed our ADSs on Nasdaq and they are traded under the symbol "BLRX."

In March 2017, we acquired Agalimmune Ltd., a private U.K.-based company, and its U.S. subsidiary, Agalimmune Inc. Agalimmune Inc. was dissolved on December 31, 2017.

Our capital expenditures for the years ended December 31, 2019, 2020 and 2021 were immaterial. Our current capital expenditures involve acquisitions of laboratory equipment, computers and communications equipment.

The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers like BioLineRx that file electronically with the SEC. The address of that site is *www.sec.gov*. We maintain a corporate website at *www.biolinerx.com*. Information contained on or accessible through our website is not a part of this Annual Report on Form 20-F, and the inclusion of our website address herein is an inactive textual reference only.

We use our website (http://www.biolinerx.com) as a channel of distribution of Company information. The information we post through this channel may be deemed material. Accordingly, investors should monitor our website, in addition to following our press releases, SEC filings and public conference calls and webcasts. The contents of our website are not, however, a part of this Annual Report on Form 20-F.

We have not had any material commitments for capital expenditures, including any anticipated material acquisition of plant and equipment or interests in other companies.

B. Business Overview

We are a late clinical-stage biopharmaceutical development company with a strategic focus on oncology. Our current development and commercialization pipeline consists of two clinical-stage therapeutic candidates – motixafortide (BL-8040), a novel peptide for the treatment of stem-cell mobilization, solid tumors, AML, and AGI-134, an immuno-oncology agent in development for solid tumors. In addition, we have an off-strategy, legacy therapeutic product called BL-5010 for the treatment of skin lesions. We have generated our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a high probability of therapeutic and commercial success. To date, except for BL-5010, none of our therapeutic candidates have been approved for marketing or sold commercially. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case-by-case basis, the commercialization of our therapeutic candidates independently.

Our Product Development Approach

We seek to develop a pipeline of promising therapeutic candidates that exhibit distinct advantages over currently available therapies or address unmet medical needs. Our resources are focused on advancing our therapeutic candidates through development and toward commercialization. Our current drug development pipeline consists of two clinical-stage therapeutic candidates.

We have established close relationships with various universities, academic and research institutions and biotechnology companies that permit us to identify and select compounds at various stages of clinical and pre-clinical development. Our approach is consistent with our objective of proceeding only with therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success.

Our Product Pipeline

The table below summarizes our current pipeline of therapeutic candidates, including the target indications and status of each candidate and our development partners:

Motixafortide

Motixafortide, is a novel, short peptide that functions as a high-affinity antagonist for CXCR4, which we are developing for the treatment of stem cell mobilization, solid tumors and AML. CXCR4 is expressed by normal hematopoietic cells and overexpressed in various human cancers where its expression correlates with disease severity. CXCR4 is a chemokine receptor that mediates the homing and retention of hematopoietic stem cells, or HSCs, in the bone marrow, and also mediates tumor progression, angiogenesis (growth of new blood vessels in the tumor), metastasis (spread of tumor to other organs) and survival. Before "motixafortide" was approved by the World Health Organization, or WHO, in 2019 as an International Nonproprietary Name, this therapeutic candidate was known as "BL-8040". In October 2021, we received WHO approval of the United States Adopted Name, or USAN, "motixafortide".

Inhibition of CXCR4 by motixafortide leads to the mobilization of HSCs from the bone marrow to the peripheral blood, enabling their collection for subsequent autologous or allogeneic transplantation in cancer patients. Clinical data has demonstrated the ability of motixafortide to mobilize higher numbers of long-term engrafting HSCs (CD34+CD38-CD45RA-CD90+CD49f+) as compared to G-CSF.

Motixafortide also mobilizes cancer cells from the bone marrow, detaching them from their survival signals and sensitizing them to chemotherapy. In addition, motixafortide has demonstrated a direct anti-cancer effect by inducing apoptosis (cell death) and inhibiting proliferation in various cancer cell models (multiple myeloma, non-Hodgkin's lymphoma, leukemia, non-small-cell lung carcinoma, neuroblastoma and melanoma).

In the field of immuno-oncology, motixafortide mediates infiltration of T-cells while reducing immune regulatory cells in the tumor microenvironment, or TME. In clinical studies, the combination of motixafortide with immune checkpoint inhibitors, such as anti PD-1, has shown T-cell activation and a reduction in tumor cell numbers.

The following is a summary of the clinical trials being carried out with motixafortide.

Stem cell mobilization

In March 2015, we reported successful top-line results from a Phase 1 safety and efficacy trial for the use of motixafortide as a novel stem cell mobilization treatment for allogeneic bone marrow transplantation at Hadassah Medical Center in Jerusalem.

In March 2016, we initiated a Phase 2 trial for motixafortide in allogeneic stem cell transplantation, conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology. In May 2018, we announced positive top-line results of this study showing, among other things, that a single injection of motixafortide mobilized sufficient amounts of CD34+ cells required for transplantation at a level of efficacy similar to that achieved by using 4-6 injections of G-CSF, the current standard of care.

In December 2017, we commenced a randomized, placebo-controlled Phase 3 registrational trial for motixafortide, known as the GENESIS trial, for the mobilization of HSCs, for autologous transplantation in patients with multiple myeloma. The trial began with a lead-in period for dose confirmation, which was to include 10-30 patients and then progress to the placebo-controlled main part, which was designed to include 177 patients in more than 25 centers. Following review of the positive results from treatment of the first 11 patients, the Data Monitoring Committee, or DMC, recommended that the lead-in part of the study be stopped and that we should move immediately to the second part. Additional positive results from the lead-in period were reported at the annual meeting of the European Society for Blood and Marrow Transplantation held in March 2019, where it was announced that HSCs mobilized by motixafortide in combination with G-CSF were successfully engrafted in all 11 patients.

In August 2020, we announced a decision to perform an interim analysis on approximately 65% of the original study sample size, primarily based on a significantly lower-than-anticipated patient-dropout rate in the study. In October 2020, we announced positive results from the interim analysis. Based on the statistically significant evidence favoring treatment with motixafortide, the study's independent DMC issued a recommendation to us that patient enrollment may be ceased immediately, without the need to recruit all 177 patients originally planned for the study. In accordance with the DMC's recommendation, study enrollment was complete at 122 patients. In May 2021, we announced positive top-line results from the Phase 3 trial. Based on an analysis of data on all 122 enrolled patients (the intent to treat population) we found highly statistically significant evidence across all primary and secondary endpoints favoring motixafortide in addition to G-CSF, as compared to placebo plus G-CSF ($p<0.0001$). The addition of motixafortide to G-CSF also allowed 88.3% of patients to undergo transplantation after only one apheresis session, compared to 10.8% in the G-CSF arm – an 8.2-fold increase. The combination was also found to be safe and well tolerated.

We continue to follow-up on the GENESIS study patients for relapse-free and overall survival. In addition, we continue to perform detailed analyses of the data according to the statistical analysis plan agreed-upon with the FDA, as well as certain post hoc analyses. In December 2021, we held a pre-NDA meeting with the FDA. The purpose of the meeting was to obtain agreement from the FDA on the content of the proposed NDA, and, in particular, to confirm that our single Phase 3 pivotal study, GENESIS, is sufficient to support an NDA submission. During the pre-NDA meeting, the FDA agreed that the proposed data package is sufficient to support an NDA submission, which we anticipate will occur in mid-2022.

In October 2021, we announced positive results from a pharmacoeconomic study evaluating the cost-effectiveness of using investigational drug motixafortide as a primary stem cell mobilization agent on top of granulocyte colony stimulating factor (G-CSF), versus G-CSF alone, in multiple myeloma patients undergoing autologous stem-cell transplantation (ASCT). The study was performed by the Global Health Economics and Outcomes Research (HEOR) team of IQVIA, and was a pre-planned study conducted in parallel with the GENESIS Phase 3 trial. The study concluded that the addition of motixafortide to G-CSF (the current standard of care) is associated with a statistically significant decrease in health resource utilization (HRU) during the ASCT process, compared to G-CSF alone. Based on the significantly higher number of mobilized cells and the lower number of apheresis sessions, lifetime estimates show quality-adjusted-life-year benefits and net cost savings of ~$17,000 (not including the cost of motixafortide), versus G-CSF alone.

In March 2022, we announced results from a follow-on pharmacoeconomic study performed by the HEOR team of IQVIA. This study indirectly evaluated the cost-effectiveness of using motixafortide as a primary stem cell mobilization agent in combination with G-CSF, against plerixafor in combination with G-CSF, in multiple myeloma patients undergoing ASCT. The additional study results show that motixafortide in combination with G-CSF, versus plerixafor in combination with G-CSF, demonstrates a statistically significant decrease in HRU during the ASCT process. Based on the significantly higher number of mobilized cells and the lower number of apheresis sessions, lifetime estimates show QALY benefits and net cost savings of ~$30,000 (not including the cost of motixafortide), versus plerixafor plus G-CSF. The study findings strengthen the assessment that the use of motixafortide in combination with G-CSF, as the potential new standard of care in mobilization for ASCT, would be a cost-effective option in the US, based on accepted willingness-to-pay (WTP) values for healthcare payers.

We believe these results, together with the highly significant and clinically meaningful data from the GENESIS trial, strongly support the potential use of motixafortide, on top of G-CSF, as the standard of care in stem cell mobilization for autologous stem cell transplantation. While we continue to seek a third party collaborator to commercialize motixafortide, we are also undertaking selected pre-commercialization activities necessary for an NDA submission, and for a timely launch, if approved by the FDA, with a view to obtaining potential FDA approval and potentially launching sales in 2023.

Solid tumors

In January 2016, we entered into a clinical collaboration with MSD (a tradename of Merck & Co., Inc., Kenilworth, New Jersey) in the field of cancer immunotherapy. Based on this collaboration, in September 2016 we initiated a Phase 2a study, known as the COMBAT/KEYNOTE-202 study, focusing on evaluating the safety and efficacy of motixafortide in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in 37 patients with metastatic pancreatic adenocarcinoma, or PDAC. The study was an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T-cells into the tumor and their reactivity. Top-line results showed that the dual combination demonstrated encouraging disease control and overall survival in patients with metastatic pancreatic cancer. In addition, assessment of patient biopsies supported motixafortide's ability to induce infiltration of tumor-reactive T-cells into the tumor, while reducing the number of immune regulatory cells.

In July 2018, we announced the expansion of the COMBAT/KEYNOTE-202 study under the collaboration to include a triple combination arm investigating the safety, tolerability and efficacy of motixafortide, KEYTRUDA ® and chemotherapy. We initiated this arm of the trial in December 2018. In December 2019, we announced that preliminary data from the study indicated that the triple combination therapy showed a high level of disease control, including seven partial responders and 10 patients with stable disease out of 22 evaluable patients. In February 2020, we completed recruiting a total of 43 patients for the study and in December 2020, we announced the final results of the study. The results of the study showed substantial improvement as compared to comparable historical results of other pancreatic cancer studies across all study endpoints. Of the 38 evaluable patients, median overall survival was 6.5 months, median progression free survival was 4.0 months, confirmed overall response rate was 13.2%, overall response rate was 21.2% and disease control rate was 63.2%. The combination was generally well tolerated, with a safety profile consistent with the individual safety profile of each component alone; adverse event and severe adverse event profiles were as expected with chemotherapy-based treatment regimens. We are currently planning next development steps for this program, including discussions with potential collaboration partners and development of a protocol for a randomized controlled study.

In August 2016, in the framework of an agreement with MD Anderson Cancer Center, or MD Anderson, we entered into an additional collaboration for the investigation of motixafortide in combination with KEYTRUDA in pancreatic cancer. The focus of this study, in addition to assessing clinical response, was the mechanism of action by which both drugs might synergize, as well as multiple assessments to evaluate the biological anti-tumor effects induced by the combination. We supplied motixafortide for this Phase 2b study, which commenced in January 2017. Final results from this study (based on a cut-off in July 2019 from 20 enrolled patients out of which 15 were evaluable) showed that the dual combination demonstrated clinical activity and encouraging overall survival in patients with metastatic pancreatic cancer. In addition, assessment of patient biopsies supported motixafortide's ability to induce infiltration of tumor-reactive T-cells into the tumor.

In October 2020, we announced that motixafortide will be tested in combination with the anti-PD-1 cemiplimab (LIBTAYO®) and standard-of-care chemotherapy (gemcitabine and nab-paclitaxel) in first-line PDAC. This investigator-initiated Phase 2 study, led by Columbia University, will initially enroll 10-12 PDAC patients, and will be expanded to a total of 40 patients following an evaluation of the initial 10-12 patients based on pre-defined criteria. The primary endpoint of the study is the overall response rate. Secondary endpoints include safety and tolerability, progression free survival, duration of clinical benefit and overall survival. Data from the study is anticipated in mid-2022 (although timelines are ultimately controlled by the independent investigator and are therefore subject to change).

AML

During 2016, we completed and reported on a Phase 2a proof-of-concept trial for the treatment of relapsed or refractory acute myeloid leukemia, or r/r AML, which was conducted on 42 patients at six world-leading cancer research centers in the United States and at five premier sites in Israel. The study included both a dose-escalation and a dose-expansion phase. Results from the trial showed positive safety and response rate data for subjects treated with a combination of motixafortide and high-dose cytarabine (Ara-C), or HiDAC. At the annual meeting of the European Hematology Association, or EHA, in June 2018, we presented positive overall survival data from the long-term follow-up part of this study. In March 2021, we completed the monitoring of long-term survival data for patients in the study and, in parallel, are evaluating our next clinical development steps in this indication.

In August 2015, we conducted a double-blind, placebo-controlled, randomized, multi-center, Phase 2b trial in Germany, in collaboration with the German Study Alliance Leukemia Group, to assess the efficacy of motixafortide in addition to standard consolidation therapy (cytarabine) in AML patients who have responded to standard induction treatment and are in complete remission. During 2020, we finalized plans with our collaboration partners to conduct an interim analysis on 2/3 (N=128) of the 194 patients originally planned in the study, all of which had already completed treatment. Based on the interim analysis, the investigational arm of motixafortide combined with cytarabine did not demonstrate a statistically significant effect in the study's primary endpoint, and therefore, the DMC recommended not to continue the study. We continue to believe in the relevance of CXCR4 as a viable target in other AML treatment lines, such as rr/AML and induction treatment, and we intend to decide on next steps in AML once we have had an opportunity to review and analyze the unblinded data, including detailed biomarker and subpopulation data, from the study.

ARDS secondary to COVID-19 and other viral infections

During the first half of 2020, we initiated the evaluation of motixafortide as a potential therapy for acute respiratory distress syndrome, or ARDS, resulting from COVID-19 and other viral infections In this regard, substantial data is emerging regarding the involvement of neutrophils, neutrophil extracellular traps (NETs), monocytes and macrophages in the development of ARDS secondary to COVID-19 and other viral infections; as well as the key involvement of CXCR4 as a mediator of those cells in the inflamed pulmonary tissue. Based on the scientific data indicating the importance of blocking the CXCR4/CXCL12 axis during ARDS, we believe that motixafortide may be of potential benefit for patients with ARDS. Following our initial evaluation, in November 2020, we announced initiation of a Phase 1b study in patients with ARDS secondary to COVID-19 and other respiratory viral infections. The study is an investigator-initiated study, led by Wolfson Medical Center, in Israel, to evaluate motixafortide in patients hospitalized with ARDS. The primary endpoint of the study is to assess the safety of motixafortide in these patients; respiratory parameters and inflammatory biomarkers will be assessed as exploratory endpoints. Up to 25 patients will be enrolled in the study, with a preliminary analysis planned after ten patients have completed the initial treatment period. Results of the preliminary analysis are expected in 2022 (although timelines are ultimately controlled by the independent investigator and are therefore subject to change).

Other matters

In addition to the above, we are currently conducting, or planning to conduct, a number of investigator-initiated, open-label studies in a variety of indications to support the interest of the scientific and medical communities in exploring additional uses for motixafortide. These studies serve to further elucidate the mechanism of action for motixafortide. The results of studies such as these are presented from time to time at relevant professional conferences.

Motixafortide has been granted three Orphan Drug Designations by the FDA: for use to mobilize HSCs from the bone marrow to peripheral blood for collection in autologous or allogeneic transplantation (granted in July 2012); for the treatment of AML (granted in September 2013); and for the treatment of pancreatic cancer (granted in February 2019). In January 2020, the European Medicines Agency, or EMA, granted Orphan Drug Designation to motixafortide for the treatment of pancreatic cancer.

AGI-134

AGI-134, a clinical therapeutic candidate in-licensed by our subsidiary, Agalimmune Ltd., is a synthetic alpha-Gal glycolipid immunotherapy in development for solid tumors. AGI-134 harnesses the body's pre-existing, highly abundant, anti-alpha-Gal antibodies to induce a hyper-acute, systemic, specific anti-tumor response to the patient's own tumor neo-antigens. This response not only kills the tumor cells at the site of injection, but also brings about a durable, follow-on, anti-metastatic immune response. In August 2018, we initiated a Phase 1/2a clinical study for AGI-134 that is primarily designed to evaluate the safety and tolerability of AGI-134 in unresectable metastatic solid tumors. The multi-center, open-label study is currently being carried out in the United Kingdom, Spain and Israel. Initial safety results from the first part of the study were announced at the beginning of September 2019; at the end of the same month, the second part of the study was commenced. Due to clinical operating issues associated with the COVID-19 pandemic, in April 2020, enrollment to the clinical trial was temporarily suspended. In August 2020, we renewed study enrollment, and in January 2022, we completed enrollment. Initial proof-of-mechanism of action and efficacy results are now expected in the second half of 2022.

Establishment of Scientific Advisory Board

In December 2021, we established a Scientific Advisory Board (SAB) to provide insight and guidance on our activities in the field of immuno-oncology. The SAB is comprised of recognized leaders in cancer immunology, intra-tumoral injections and clinical development.

Listed in alphabetical order, the founding SAB members are: Ronald Levy, MD, the Robert K. and Helen K. Summy Professor and Director of the Lymphoma Program at Stanford University School of Medicine, Palo Alto, CA; Aurélien Marabelle, MD, PhD, Clinical Director, Cancer Immunotherapy Program, Gustave Roussy, Paris, France and Director, Translational Research Laboratory in Immunotherapy, INSERM, Paris, France; Ignacio Melero MD, PhD, Professor of Immunology at the Academic Hospital of Navarra, Spain and at the Center for Applied Medical Research (CIMA) of the University of Navarra, Spain; and Jon Wigginton, MD, Chair of the SAB and Senior Advisor at Cullinan Oncology, former Chief Medical Officer of MacroGenics, and former Therapeutic Area Head, Immuno-Oncology, Early Clinical Research at Bristol-Myers Squibb.

BL-5010

Our commercialized, legacy therapeutic product, BL-5010, is a customized, proprietary pen-like applicator containing a novel, acidic, aqueous solution for the non-surgical removal of skin lesions. In December 2014, we entered into an exclusive out-licensing arrangement with Perrigo Company plc, or Perrigo, for the rights to BL-5010 for over-the-counter, or OTC, indications in Europe, Australia and additional selected countries. In March 2016, Perrigo received CE Mark approval for BL-5010 as a novel OTC treatment for the non-surgical removal of warts. The commercial launch of products for treatment of this first OTC indication (warts/verrucas) commenced in Europe in the second quarter of 2016. Since then, Perrigo has invested in improving the product and during 2019 launched an improved version of the product in several European countries. In March 2020, we agreed that Perrigo could relinquish its license rights for certain countries that had been included in its territory according to the original license agreement and was also no longer obligated to develop, obtain regulatory approval for and commercialize products for a second OTC indication. In turn, in March 2020, we agreed with our licensor of the rights to BL-5010, Innovative Pharmaceutical Concepts (IPC) Inc., or IPC, to return to IPC those license rights no longer out-licensed to Perrigo as a result of the agreement described in the preceding sentence, in consideration of the payment to us of royalties or fees on sublicense receipts.

Our Strategy

Our objective is to become a leader in the development of novel therapeutics for the treatment of cancer. We have successfully advanced a number of therapeutic candidates into clinical development. We intend to commercialize our two clinical candidates, motixafortide and AGI-134, and any future candidates either on our own or through out-licensing or co-development arrangements with third parties that may perform any or all of the following tasks: completing development, securing regulatory approvals, securing reimbursement codes from insurance companies and health maintenance organizations, manufacturing and/or marketing. If appropriate, we may also enter into co-development and similar arrangements with respect to any therapeutic candidate with third parties or commercialize a therapeutic candidate ourselves.

Therapeutic Candidates

Motixafortide

The following paragraphs are a high-level summary of the therapeutic areas we are currently investigating for motixafortide:

Stem cell mobilization. High-dose chemotherapy followed by stem cell transplantation has become an established treatment modality for a variety of hematologic malignancies, including multiple myeloma (MM), as well as various forms of lymphoma and leukemia. Stem cells are mobilized from the bone marrow of the patient (i.e., autologous transplant) or donor (i.e., allogeneic transplant) using granulocyte-colony stimulating factor (G-CSF), harvested from the peripheral blood by apheresis, and infused to the patient after intensive myeloablation (chemo/radiotherapy). In 2019, approximately 45,000 autologous transplants were conducted in the US and EU. The goal of collection is approximately 5-6M cells/kg for MM patients. Plerixafor (in combination with G-CSF) can be used upfront, or as a rescue therapy for those patients that did not achieve the target collection. Today, it is estimated that approximately 55-60% of patients undergoing autologous transplantation in the US receive plerixafor on top of G-CSF. A recent market assessment which we commissioned through a third party vendor estimates the value of the U.S. stem cell mobilization market at ~$360M in 2021.

Solid tumors. Novel, emerging therapeutic approaches for targeting solid tumors are being developed and tested. Combinational therapies of immune checkpoint inhibitors with immuno-oncology supporting agents, with or without chemotherapy, are among the most promising experimental treatments for solid malignancies.

Pancreatic cancer has a low rate of early diagnosis, a high mortality rate and a poor five-year survival prognosis. Symptoms are usually non-specific and as a result, pancreatic cancer is often not diagnosed until it reaches an advanced stage. Once the disease has metastasized, or spread to other organs, it becomes especially hard to treat. Each year, about 185,000 individuals globally are diagnosed with this condition; and in 2021, the Surveillance, Epidemiology and End Results program, or SEER, of the National Cancer Institute estimated that in the United States there would be approximately 60,000 individuals diagnosed with pancreatic cancer. The overall five-year survival rate among pancreatic cancer patients is 7-8%, which constitutes the highest mortality rate among solid tumor malignancies; among those diagnosed with metastatic disease, the overall five-year survival rate is only 3%. Recent developments that have improved the survival in many cancer types have not been effective for pancreatic cancer patients, highlighting the need for the development of new therapeutic options.

Furthermore, second-line patients that were diagnosed already with metastatic disease have very few therapeutic options. The only approved regimen for second-line patients is Onivyde® in combination with 5FU and LV. For these Stage IV at diagnosis patients reaching second-line therapy, median overall survival is only 4.7 months (Macarulla et al, Pancreas 2020).

Acute Myeloid Leukemia (AML), is a cancer of the blood and bone marrow and is the most common type of acute leukemia in adults. The SEER of the National Cancer Institute estimated that in the United States there would be approximately 21,000 new cases of AML diagnosed during 2021. AML is generally a disease of older people and is uncommon before the age of 45. The average age of newly diagnosed AML patients is 68. The first treatment line for patients with AML includes a combination of chemotherapy drugs and is called induction treatment. The majority of patients achieving complete response, or CR, will eventually relapse, most of them during the first three years of receiving induction chemotherapy. The next step of treatment after relapse is salvage therapy. A common approach is to induce a second remission and follow treatment with allogeneic hematopoietic stem cell transplantation or allo-SCT to consolidate second CR in eligible patients, although the duration of second remission is usually short than the first remission. Due to relapsed or refractory disease (where the disease is not responsive to standard treatments), the overall five-year survival rate for AML ranges between 10% and 40%. With current standard chemotherapy treatments, approximately 25-30% of adults under the age of 60 will survive more than five years, while in the elderly patient population, only less than 10% will survive more than five years.

Regulatory Approvals.

United States

In September 2013, the FDA granted an Orphan Drug Designation to motixafortide as a therapeutic for the treatment of AML. In January 2014, the FDA granted an Orphan Drug Designation to motixafortide for use, in combination with G-CSF, in mobilizing human stem cells from the bone marrow to the peripheral blood for collection for autologous or allogeneic (donor-based) transplantation. In January 2015, the FDA modified this Orphan Drug Designation for motixafortide for use either as a single agent or in combination with G-CSF. In February 2019, the FDA granted Orphan Drug Designation to motixafortide for use in the treatment of pancreatic cancer. Orphan Drug Designation is granted to therapeutics intended to treat rare diseases that affect not more than 200,000 people in the United States. Orphan Drug Designation entitles the sponsor to a seven-year marketing exclusivity period and clinical protocol assistance with the FDA, as well as federal grants and tax credits.

European Union

In January 2020, the EMA granted an Orphan Drug Designation to motixafortide for the treatment of pancreatic cancer. The EMA grants orphan medicinal product designation to investigational drugs intended to treat, prevent or diagnose a life-threatening or chronically debilitating disease affecting fewer than five in 10,000 people in the EU and for which no satisfactory treatment is available or, if such treatment exists, the medicine must be of significant benefit to those affected by the condition. Orphan medicinal product designation provides regulatory and financial incentives for companies to develop and market therapies, including ten years of market exclusivity, protocol assistance, fee reductions and EU-funded research.

Preclinical Results.

In vitro and in vivo studies have shown that motixafortide binds CXCR4 with high affinity (7.9 pM) and occupies it for prolonged periods of time (>48h). Animal cancer models have shown that motixafortide mobilizes cancer cells from the bone marrow and may therefore detach these cells from survival signals in the bone marrow microenvironment as well as sensitize them to chemo- and bio-based anti-cancer therapies. In addition, motixafortide directly induces apoptosis of cancer cells. Motixafortide was efficient, both alone and in combination with chemotherapy, in reducing malignant bone marrow cells and stimulating their cell death.

In August 2013, we announced that motixafortide has been shown in preclinical trials to be effective for the treatment of thrombocytopenia, or reduced platelet production.

In December 2013, we presented preclinical data at the annual meeting of the American Society of Hematology (ASH), showing that motixafortide directly inhibits AML, cell growth and induces cell death, both in cell cultures and in mice engrafted with human AML cells. In addition, motixafortide showed the ability to induce mobilization of AML cells from the bone marrow into the blood circulation, thereby enhancing the chemotherapeutic effect of ARA-C (one of the standard-of-care chemotherapies for AML). The data also showed that motixafortide's effects were even more robust in cells harboring the FLT3 mutation, and a synergistic effect was observed when motixafortide was combined with the FLT3 inhibitor AC220 (Quizartinib).

At the annual meeting of ASH in December 2016, detailed preclinical data on the mechanism-of-action by which motixafortide directly induces apoptosis of AML cells was presented by Prof. Amnon Peled of the Hadassah Medical Center and Biokine. The results of the preclinical studies showed that motixafortide treatment in vivo triggered mobilization of AML blasts from their protective bone marrow microenvironment and induced their terminal differentiation, further supporting the data we presented at the American Association for Cancer Research (AACR) annual conference earlier in 2016. In addition, the studies illustrate how motixafortide increases the expression and activity of a special class of microRNA precursors termed miR-15a/16-1. These microRNA molecules have been previously linked to cancer and shown to suppress the activity of several tumor-related pro-survival proteins. Therefore, by increasing the expression of miR-15a/16-1 microRNA molecules, motixafortide decreases the expression of tumor-survival proteins and promotes tumor cell death. Importantly, in both in vitro and in vivo experiments, motixafortide was found to synergize with a selective Bcl-2 inhibitor (Venetoclax) and an FLT3 inhibitor (Quizartinib, also known as AC220) in inducing AML cell death, pointing at potential drug combination treatments.

At the ASCO-SITC Clinical Immuno-Oncology Symposium, or ASCO-SITC, in January 2018, we presented preclinical data showing that motixafortide augments the ability of the immune system to fight cancer by increasing the infiltration of anti-tumor-specific T-cells into the TME, resulting in decreased tumor growth and prolonged survival in a murine model of cancer. In the preclinical study, a murine model of cancer was used to assess the effects of motixafortide in combination with a cancer vaccine that primes the immune system against the tumor. The results of the study show that combining motixafortide with the cancer vaccine leads to a significantly enhanced anti-tumor immune response, which attenuates tumor growth and prolongs mouse survival better than either agent administered alone. The results go on to demonstrate that motixafortide significantly increases the abundance of tumor-specific T-cells in the TME, suggesting an explanation for the enhanced efficacy of the combination over either agent when administered alone.

At the annual meeting of SITC in November 2019, we presented positive preclinical results further elucidating the mechanism of action of motixafortide in combination with an anti PD-1 and chemotherapy. The pre-clinical study assessed the effects of motixafortide, anti-PD-1 and chemotherapy (Irinotecan, Fluorouracil and Leucovorin), both alone and in various combinations, on tumor growth and immune cell constitution in a mouse model for pancreatic cancer. The key findings were that the triple combination of motixafortide+anti-PD-1+chemotherapy (a) had a significantly better effect on tumor growth compared to chemotherapy alone or any dual combination with chemotherapy and (b) showed the best effect in modulation of the TME, resulting in reduction in immunosuppressive cells, and accompanied by increase of activated T effector cells.

At the annual meeting of ASH in December 2021, we presented findings from in vivo and in vitro pre-clinical studies demonstrating that motixafortide acts as an immunomodulator by affecting the biology of regulatory T-cells (Tregs), and immunosuppressive T-cells, supporting biomarker findings from our COMBAT Phase 2 study in pancreatic cancer patients.

Clinical Trials

Stem cell mobilization

Phase 1/2a and Phase 1 study

In a Phase 1/2a, open-label, dose escalation, safety and efficacy clinical trial in 18 multiple myeloma patients, motixafortide demonstrated a good safety profile at all doses tested and was highly effective in combination with G-CSF, in the mobilization of hematopoietic stem cells from the bone marrow to the peripheral blood for autologous transplantation. All patients receiving transplants (n=17) exhibited rapid engraftment, with median time to neutrophil and platelet recovery of 12 and 14 days, respectively, at the highest dose given (0.9 mg/kg).

In March 2015, we announced successful top-line results from a Phase 1 trial for motixafortide as a novel treatment for the mobilization of stem cells from the bone marrow to the peripheral blood circulation in healthy volunteers, where they can be potentially harvested for allogeneic transplant supporting the treatment of hematological indications. The study was conducted at the Hadassah Medical Center in Jerusalem and consisted of two parts. The first part of the study was a randomized, double-blind, placebo-controlled, dose-escalation study in three cohorts of eight participants each, with each participant receiving two consecutive injections of motixafortide. Results show that motixafortide is safe and well tolerated up to the maximal tested dose of one mg/kg, and that dramatic mobilization of CD34+ hematopoietic stem and progenitor cells, or HSPCs, was observed across all doses tested. The robust mobilization supports the further use of a single injection of motixafortide for HSPC collection.

In the second part of the Phase 1 study, eight healthy participants received a single injection of motixafortide at the highest tested dose of 1 mg/kg, and four hours later underwent a single, standard leukapheresis procedure. Robust and rapid stem cell mobilization was evident in all treated participants, supporting a novel approach to stem cell collection. The median level of collected stem cells was higher than 11 x 10^6 cells per kg, which is more than two-fold higher than the target concentration, and five-fold higher than the minimum concentration, necessary for transplantation. In addition, the level of HPSCs in the peripheral blood circulation 24 hours after injection of motixafortide enabled an additional apheresis on Day 2, if needed. These data support the use of motixafortide as a single-agent, single-injection, one-day regimen for the collection of stem cells.

Phase 2 study

In March 2016, we initiated a Phase 2 trial for motixafortide as a novel approach for the mobilization and collection of bone marrow stem cells from the peripheral blood circulation for allogeneic bone marrow transplantation. The open-label study was conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology, and enrolled up to 24 donor/recipient pairs, aged 18-70. The trial was designed to evaluate the ability of motixafortide, as a single agent, to promote stem cell mobilization for allogeneic transplantation. On the donor side, the primary endpoint of the study was the ability of a single injection of motixafortide to mobilize 2x10^6 CD34 cells for transplantation following up to two apheresis collections. On the recipient side, the study aimed to evaluate the functionality and engraftment following transplantation of the motixafortide collected graft. The study also evaluated the safety and tolerability of motixafortide in healthy donors, as well as graft durability, the incidence of grade 2-4 acute graft versus host disease, or GVHD, chronic GVHD, relapse and other recipient-related parameters in patients who have undergone transplantation of hematopoietic cells mobilized with motixafortide.

In May 2018, we announced positive results from the study. Single-agent treatment with motixafortide showed efficacy similar to standard of care (currently, a four- to five-day treatment cycle with G-CSF and a one- to two-day apheresis procedure) in only one administration of motixafortide. In addition, motixafortide showed results that were comparable to the standard of care in recipient engraftment, with all transplanted recipients successfully engrafting with motixafortide-mobilized grafts.

Phase 3 study

In December 2017, we initiated a Phase 3 registration study for motixafortide in autologous stem cell mobilization. The trial, known as the GENESIS study, is a randomized, placebo-controlled, multicenter study, evaluating the safety, tolerability and efficacy of motixafortide and G-CSF, compared to placebo and G-CSF, for the mobilization of HSCs for autologous transplantation in multiple myeloma patients. The study began with an open-label, single-arm lead-in period, which was to include 10-30 patients in order to assess safety and efficacy following treatment with motixafortide plus G-CSF. Results of the first 11 patients showed that motixafortide in combination with standard G-CSF treatment is safe, tolerable and efficacious, demonstrating the potential of motixafortide treatment to reduce the number of administrations and apheresis sessions, as well as hospitalization costs, related to the preparation of multiple myeloma patients for autologous HSC transplantation. Following its review of the positive lead-in results, the DMC recommended that the lead-in part of the study be stopped and that we move immediately to the placebo-controlled main part, which was designed to include 177 patients in more than 15 centers. Additional positive results from the lead-in period were reported at the annual meeting of the European Society for Blood and Marrow Transplantation held in March 2019, where it was announced that HSCs mobilized by motixafortide in combination with G-CSF were successfully engrafted in all 11 patients. Treatment in the main part of the study included five to eight days of G-CSF, with a single dose of motixafortide or placebo on Day 4 and an optional additional dose of motixafortide or placebo on Day 6. Apheresis for stem cell collection was performed on day 5. Further apheresis sessions were conducted if needed in order to reach the benchmark of ≥ 6 million mobilized CD34+ cells. The primary objective of the study was to demonstrate that motixafortide on top of G-CSF is superior to G-CSF alone in the ability of mobilize ≥ 6 million CD34+ cells in up to two apheresis sessions. Secondary objectives included time to engraftment of neutrophils and platelets and durability of engraftment, as well as other efficacy and safety parameters.

In August 2020, we announced a decision to perform an interim analysis on approximately 65% of the original study sample size, primarily based on a significantly lower-than-anticipated patient-dropout rate in the study. In October 2020, we announced positive results from the interim analysis. Based on the statistically significant evidence favoring treatment with motixafortide, the study's independent DMC issued a recommendation to us that patient enrollment may be ceased immediately, without the need to recruit all 177 patients originally planned for the study. In accordance with the DMC's recommendation, study enrollment was complete at 122 patients.

In May 2021, we announced positive top-line results from the Phase 3 trial. An analysis of data on all 122 enrolled patients (the intent to treat, or ITT, population) found highly statistically significant evidence across all primary and secondary endpoints favoring motixafortide in addition to G-CSF, as compared to placebo plus G-CSF. In addition, the combination was found to be safe and well tolerated. The primary endpoint of the study demonstrated a 4.9-fold increase and treatment effect of 54.6% (95% CI 39.7-69.5%; $p<0.0001$) in the proportion of patients in the treatment arm, as compared to the control arm, mobilizing ≥ 6 million CD34+ cells/kg in up to two apheresis sessions, and after only one administration of motixafortide. This translated to an odds-ratio of 12.9. The study also achieved its main secondary endpoint, demonstrating a 14.1-fold increase and treatment effect of 61.7% (95% CI 49.5-73.8%; $p<0.0001$) in the proportion of patients in the treatment arm, as compared to the control arm, who mobilized ≥ 6 million CD34+ cells/kg in just one apheresis session. This translated to an odds-ratio of 56.0. Other important data from the study include median number of CD34+ cells collected on the first day of apheresis (~11 million in the treatment arm vs ~2 million in the control arm) – a >5-fold increase. The addition of motixafortide to G-CSF also allowed 88.3% of patients to undergo transplantation after only one apheresis session, compared to 10.8% in the G-CSF arm – an 8.2-fold increase. Engraftment endpoints, including the number of days needed for engraftment, success of engraftment and the durability of engraftment 100 days post-transplant, further support the study's success.

Solid tumors

COMBAT-KEYNOTE-202 Dual Combination Study

In January 2016, we entered into a clinical collaboration with MSD in the field of cancer immunotherapy. In the framework of this collaboration, in September 2016 we initiated a Phase 2a study, known as the COMBAT/KEYNOTE-202 study, focusing on evaluating the safety and efficacy of motixafortide in combination with KEYTRUDA, MSD's anti-PD-1 therapy, in patients with metastatic PDAC. Findings in the field of immuno-oncology suggest that CXCR4 antagonists such as motixafortide may be effective in inducing the migration of anti-tumor T-cells into the TME. KEYTRUDA is a humanized monoclonal antibody that works by blocking co-inhibitory T-cell activation signals, thereby increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes, which may affect both tumor cells and healthy cells. The study was an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of motixafortide and KEYTRUDA as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T-cells into the tumor and their reactivity. According to the terms of our collaboration agreement with MSD, we sponsored and performed the COMBAT/KEYNOTE-202 study and MSD supplied its compound for purposes of the study. Upon completion of the study, or at any earlier point, both parties will have the option to expand the collaboration to include a pivotal registration study.

Partial results from the motixafortide monotherapy portion of this trial were presented at ASCO-GI in January 2018. These results showed that motixafortide was safe and well-tolerated, and that it induced an increase in the number of total immune cells in the peripheral blood, while the frequency of peripheral blood Tregs, known to impede the anti-tumor immune response, was decreased. In addition, analysis of available biopsies (N=7) showed infiltration of effector T-cells, known to attack cancer cells, into the tumor periphery and TME. In this regard, the results show up to a 15-fold increase in CD3+ T-cells, and up to a two-fold increase in CD8+ T-cells, in the TME of 43% (3/7) of the patients, after five days of motixafortide monotherapy.

In October 2018, we announced encouraging top-line results from the dual combination arm of the COMBAT/KEYNOTE-202 study at the European Society for Medical Oncology 2018 Congress. The data showed that the treatment regimen was safe and well tolerated. The disease control rate (patients exhibiting a response or stable disease) was 34.5% for the evaluable population (N=29), including one patient (3.4%) with a partial response showing a 40% reduction in tumor burden, as well as nine patients (31%) with stable disease, with a median treatment time of 72 days (37-267). Median overall survival (OS) in all patients (N=37) was 3.3 months with a six-month survival rate of 34.4%. A significant observation was made in the subpopulation of patients receiving the study drugs as a second-line treatment (N=17), where the median overall survival was 7.5 months, with a six-month survival rate of 51.5%. This compared favorably with historical median overall survival data of 6.1 months for the only currently approved second-line PDAC treatment (a chemotherapy combination of Onivyde®, 5-FU and leucovorin). Additional data from in-depth analyses of biopsies taken at screening and following monotherapy or combination treatment of motixafortide and KEYTRUDA demonstrate that in 75% of the available biopsies, motixafortide treatment promotes an increase in the number of infiltrating CD4+, CD8+ and CD8+Granzyme B+ cytotoxic T-cells. The greatest improvement in T-cell infiltration was observed following combination treatment of motixafortide and KEYTRUDA and was correlated with stable disease for eight cycles of treatment. Furthermore, increased infiltration of activated CD4 and CD8 T-cells was accompanied by a pronounced decrease in the number of tumor cells, as well as by a decrease in myeloid-derived suppressor cells, a cell type known to impede the antitumor immune response.

COMBAT-KEYNOTE-202 Triple Combination Study

As a result of the encouraging data, the collaboration with MSD was expanded to include an additional cohort that tested the effect of the triple combination of motixafortide, KEYTRUDA and chemotherapy (Onivyde®/5-fluorouracil/leucovorin). We initiated this additional arm of the trial in December 2018 to investigate the safety, tolerability and efficacy of this triple combination. The triple combination arm focused on second-line pancreatic cancer patients and included approximately 40 patients with unresectable metastatic PDAC who have progressed following first-line therapy prior to enrollment. Patients received motixafortide monotherapy priming treatment for five days, followed by repeat cycles of the combination of chemotherapy, KEYTRUDA and motixafortide until progression. The primary endpoint of the study was the objective response rate (ORR) assessed by RECIST v1.1 criteria. Secondary endpoints included overall survival, progression free survival, and the disease control rate.

At the European Society of Medical Oncology Immuno-Oncology Congress (ESMO IO) 2019 in December 2019, we presented partial results from the triple combination arm of the study. Out of 36 enrolled patients, 30 patients were evaluable for safety and 22 were evaluable for efficacy. The best response for the evaluable population of 22 patients showed 7 partial response (PR) and 10 stable disease (SD) patients, resulting in an overall response rate (ORR) of 32% and a disease control rate (DCR) of 77%. These data compared favorably with the current chemotherapy standard-of-care treatment (Onivyde®/5-fluorouracil/leucovorin) in second-line patients with ORR of 17% and DCR of 52%. The combination showed continuity of effect, in that 5 patients with stable disease became partial responders as treatment continued. Out of the 7 partial responders, 5 were still on treatment as of the presentation date, with a current maximum treatment time of 330+ days; and 4 responders showed a reduction in tumor burden of >50%. The median duration of clinical benefit until progression for the 17 patients with disease control (7 PR and 10 SD patients) was 7.8 months. The combination was generally well tolerated, with a safety profile consistent with the individual safety profile of each component alone; adverse event and severe adverse event profiles were as expected with chemotherapy-based treatment regimens.

In February 2020, we completed recruiting a total of 43 patients for the triple combination study and in December 2020, we announced the final results of the study. The results of the study showed substantial improvement as compared to comparable historical results of other pancreatic cancer studies across all study endpoints. Of the 38 evaluable patients, median overall survival was 6.5 months (versus comparable historical data of 4.7 months), median progression free survival was 4.0 months (versus comparable historical data of 2.7-3.1 months), confirmed overall response rate was 13.2% (versus comparable historical data of 7.7%), overall response rate was 21.2% (versus comparable historical data of 16%) and disease control rate was 63.2% (versus comparable historical data of 29-52%). The combination was generally well tolerated, with a safety profile consistent with the individual safety profile of each component alone; adverse event and severe adverse event profiles were as expected with chemotherapy-based treatment regimens. We are currently planning next development steps for this program, including discussions with potential collaboration partners and development of a protocol for a randomized controlled study.

MD Anderson Cancer Center Study

In August 2016, we entered into an agreement with MD Anderson in regard to an additional collaboration for the investigation of motixafortide in combination with KEYTRUDA in pancreatic cancer. The study was conducted as an investigator-sponsored study, as part of a strategic clinical research collaboration between Merck and MD Anderson aimed at evaluating KEYTRUDA in combination with various treatments and novel drugs, including motixafortide. The open-label, single center, single-arm Phase 2b study focused on the mechanism of action by which both drugs might synergize. In addition to assessing clinical response, the study included multiple assessments to evaluate the biological anti-tumor effects induced by the combination. We supplied motixafortide for the study, which commenced in January 2017.

Final results of the MD Anderson study were presented at the SITC annual meeting in November 2019. Of the 20 patients enrolled, 15 were evaluable for the primary endpoint of radiologic response. Of these 15 evaluable patients, one patient showed a partial response, two patients had stable disease and 12 patients experienced disease progression, resulting in a disease control rate of 20%. The overall median time to progression was two months, while the median time to progression for patients showing disease control was seven months. Median overall survival was seven months, while median survival for the patients showing disease control was 12 months. The combination was generally well tolerated with injection site discomfort being the most commonly reported adverse event. Four patients experienced grade 3 toxicities and one patient had a grade 4 dyspnea.

Investigator-Initiated LIBTAYO Study

In October 2020, we announced that motixafortide will be tested in combination with the anti-PD-1 cemiplimab (LIBTAYO®) and standard-of-care chemotherapy (gemcitabine and nab-paclitaxel) in first-line PDAC. This investigator-initiated Phase 2 study, led by Columbia University, will initially enroll 10-12 PDAC patients, and will be expanded to a total of 40 patients following an evaluation of the initial 10-12 patients based on pre-defined criteria. The primary endpoint of the study is the overall response rate. Secondary endpoints include safety and tolerability, progression free survival, duration of clinical benefit and overall survival. Data from the study is anticipated in mid-2022 (although timelines are ultimately controlled by the independent investigator and are therefore subject to change).

AML

Phase 2a Study

During 2016, we completed and reported on the results of a Phase 2a clinical trial studying the use of motixafortide for the treatment of relapsed/refractory AML, or r/r AML. The study was conducted at six sites in the United States, including MD Anderson in Houston, Memorial Sloan-Kettering Cancer Center in New York, Mayo Clinic in Jacksonville, Johns Hopkins University in Baltimore, Northwestern Memorial Hospital in Chicago and Washington University in St. Louis, as well as at five well-known sites in Israel. The study was an open-label study under an IND, designed to evaluate the safety and efficacy profile of repeated escalating doses of motixafortide in combination with HiDAC in adult subjects with r/r AML. The study was comprised of two parts – a dose escalation Phase and an expansion Phase at the highest tolerated dose found during the escalation Phase. The primary endpoints of the study were the safety and tolerability of the drug. Secondary endpoints included the pharmacokinetic profile of the drug and an efficacy evaluation, indicated by the extent of mobilization of cancer cells from the bone marrow to the peripheral blood, the level of cancer cell death (apoptosis) and clinical responses.

Final results for the Phase 2a trial were presented at the annual meetings of the Society of Hematologic Oncology and ASH in September and December 2016, respectively. The reported data set includes 45 patients, including three compassionate-use patients treated at the study sites under the identical treatment protocol. The majority of patients in the study were heavily pretreated, with 45% of patients being refractory to one or two remission induction treatments, 19% of patients having relapsed after a short first remission of less than 12 months, and 17% of patients having undergone two or more relapses. In addition, the treated patient population included patients that had relapsed post allogeneic stem cell transplantation (17%), as well as secondary AML patients (24%), both conditions which represent difficult-to-treat populations with poor prognoses.

The results showed that treatment with motixafortide in combination with HiDAC, was safe and well tolerated at all doses tested up to and including the highest dose level of 2.0 mg/kg. Response to treatment was associated with efficient CXCR4 inhibition, resulting in high mobilization of blasts. The composite complete remission rate, including both CR and CRi, was 38% in subjects receiving up to two cycles of motixafortide treatment at doses of 1 mg/kg and higher (n=39). In the 1.5 mg/kg dose selected for the expansion Phase of the study (n=23), the composite complete remission rate was 39%. These response rates were superior to the historical response rate of approximately 19% reported for high-risk AML patients treated with Ara-C alone in Phase 3 randomized trials. The ongoing follow-up of patients participating in the study's expansion Phase and responding to the combination treatment suggests long durability of the remissions achieved. Results further showed that motixafortide monotherapy had a substantial therapeutic effect. Treatment with motixafortide as a single agent triggered robust mobilization of AML blasts from the bone marrow to the peripheral blood stream, and the extent of mobilization was correlated with a positive response to treatment. The preferential mobilization of AML blasts over normal cells (4.7-fold vs. 1.4-fold, respectively) was further confirmed by analysis using the fluorescence in situ hybridization, or FISH, technique in a subset of patients. In addition, motixafortide monotherapy resulted in a 40% increase in AML blast apoptosis.

In June 2018, at the 23rd Congress of the EHA in Stockholm, Sweden, we reported long-term survival data from the study that showed significantly enhanced overall survival of r/r AML patients treated with a combination of motixafortide and HiDAC. The response rate for all dosing levels was 29% and median overall survival was 9.1 months, compared with historical data on overall survival of 6.1 months for HiDAC alone. In addition, a statistically significant correlation between patient response and the mobilization of AML blasts was reported. Responding patients demonstrated a clear and significant increase in the number of AML blasts in the peripheral blood following motixafortide treatment, whereas non-responding patients were largely unaffected. In patients receiving the 1.5 mg/kg dose selected for expansion (n=23), the response rate was 39% and median overall survival was 10.7 months with one-year, two-year and three-year survival rates of 38.1%, 23.8% and 23.8%, respectively. Furthermore, median overall survival for responding patients at the 1.5 mg/kg dose (n=9) was 21.8 months, with one-year, two-year and three-year survival rates of 66.7%, 44.4% and 44.4%, respectively. Responding patients also demonstrated a statistically significant mean 6.3-fold increase (p=0.003) in the number of AML blasts in the peripheral blood following motixafortide monotherapy treatment, whereas in non-responding patients the mean-fold increase was minor and non-significant (1.66-fold; p=0.21).

BLAST Study

We also investigated a second AML treatment line – consolidation therapy – in a large randomized, controlled Phase 2b trial in Germany, known as the BLAST study. This study examined motixafortide as part of a second-stage treatment, termed consolidation therapy (cytarabine), to improve outcomes for the approximately 70% of AML patients who achieved remission after the standard initial treatment regimen, known as induction therapy. The consolidation therapy was aimed at eliminating the minimal residual disease left in the bone marrow after induction therapy that can lead to relapse in 40-60% of the patients within 12-18 months after entering remission.

The Phase 2b trial, which was conducted in collaboration with the University of Halle as sponsor and with the participation of two large leukemia study groups in Germany, was a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of motixafortide in addition to standard consolidation therapy in AML patients. The primary endpoint of the study was to compare the RFS time in AML subjects in their first remission during a minimum follow-up time of 18 months after randomization. In addition, pharmacodynamic measurements were conducted in order to assess the minimal residual disease, and biomarker analyses was performed to identify predictors of motixafortide response. The study, which was carried out at 29 sites in Germany. AML patients between 18 and 75 years of age with documented first remission were randomized in a 1:1 ratio to receive HiDAC, either with motixafortide or with a matching placebo, as consolidation therapy.

During 2020, we finalized plans with our collaboration partners to conduct an interim analysis on 2/3 (N=128) of the 194 patients originally planned in the study, all of which had already completed treatment. In November 2020, we announced that based on the interim analysis, the investigational arm of motixafortide combined with cytarabine did not demonstrate a statistically significant effect in the study's primary endpoint, and therefore, the DMC recommended not to continue the study. Based on the DMC's recommendation, we terminated the study. We continue to believe in the relevance of CXCR4 as a viable target in other AML treatment lines, such as rr/AML and induction treatment, and we intend to decide on next steps in AML once we have had an opportunity to review and analyze the unblinded data, including detailed biomarker and subpopulation data, from the study.

Other clinical results

At the annual meeting of ASH in December 2017, clinical data supporting motixafortide as a robust mobilizer of HSCs associated with long-term engraftment was presented by Prof. Amnon Peled. HSCs are cells found in the bone marrow, peripheral blood or umbilical cord blood that are responsible for generation and replenishment of all blood cell progenitors and eventually mature cells. It is therefore believed to be beneficial for a variety of therapeutic purposes, such as transplantation for people with hematological malignancies or for the therapy of blood or immune system disorders. The success of long-term HSC engraftment depends largely on the amount and quality of HSCs (CD34+ CD38- CD45RA- CD90+ CD49f+). The data presented demonstrate that human CD34+ cells from motixafortide-mobilized grafts contain high numbers of HSC (CD34+, CD38-, CD45RA-, CD90+, CD49f+) associated with long-term engraftment, compared to cells mobilized by granulocyte colony stimulating factor (G-CSF). An associated in vivo study further showed that motixafortide-mobilized HSCs can successfully engraft the bone marrow and spleen of immunodeficient mice. In addition, a robust long-term engraftment of motixafortide-mobilized human CD34+ cells was seen in these mice in primary and secondary transplants.

AGI-134

AGI-134 entered our pipeline following our acquisition of Agalimmune in March 2017. The compound is a synthetic alpha-gal immunotherapy in development for solid tumors. AGI-134 harnesses the body's pre-existing, highly abundant, anti-alpha-gal, or anti-Gal, antibodies to induce a systemic, specific anti-tumor response to the patient's own tumor neo-antigens. This response not only kills the tumor cells at the site of injection, but also brings about a durable, follow-on, anti-metastatic immune response. Alpha-gal is a cell-surface carbohydrate antigen that is not expressed by humans, unlike virtually all other mammals and bacteria. Therefore, humans universally produce and maintain high levels of anti-Gal antibodies, due to exposure to alpha-gal on bacteria in the digestive system.

AGI-134 is injected into the tumor, where it coats the tumor cell membranes, resulting in alpha-gal being exposed on the tumor cell surface. Anti-Gal antibodies bind to the alpha-gal part of AGI-134 to produce an initial immune response that activates complement-dependent and antibody-dependent cellular cytotoxicity (cell death). This cytotoxicity generates immune-tagged cells and cellular debris that trigger an uptake of tumor-associated antigens by antigen-presenting cells (APCs). These APCs induce a follow-on systemic immune response by the activation and clonal expansion of T-cells to the patient's own neo-antigens. This approach not only targets the primary injectable tumor but has also demonstrated efficacy against existing distant secondary tumors. Furthermore, the mechanism of action suggests the potential of long-term protection against future metastases.

AGI-134 has completed numerous proof-of-concept studies, demonstrating regression of established primary tumors after injection with AGI-134 and robust protection against the development of secondary tumors in a model of melanoma with a single dose only. Synergy has also been demonstrated in the same model when combined with a PD-1 immune checkpoint inhibitor, offering the potential to broaden the utility of such immunotherapies and improve the rate and duration of responses in multiple cancer types. A 28-day, repeated-administration GLP toxicology study in monkeys with AGI-134 has also been successfully completed.

At ASCO-SITC in January 2018, we presented preclinical findings demonstrating successful results in the treatment of primary tumors. Intratumoral administration of AGI-134 induced regression of established tumors in two murine melanoma models. Moreover, treatment with AGI-134 showed a beneficial effect on survival, compared to the control group, with fewer mice dying or requiring euthanasia due to tumor burden. In addition, the results show that injection of AGI-134 into the tumors induces activation of the complement system, an important component of the innate immune system. Activation of the complement system within tumors by AGI-134 is predicted to destroy tumor cells and create a pro-inflammatory TME that attracts and activates other immune cells, ultimately resulting in adaptive anti-tumor immunity.

In August 2018, we initiated a Phase 1/2a clinical study for AGI-134 that is primarily designed to evaluate the safety and tolerability of AGI-134 given as monotherapy in unresectable metastatic solid tumors. Additional objectives are to perform a wide array of biomarker studies, to demonstrate the mechanism of AGI-134 and to assess its efficacy by clinical and pharmacodynamic parameters. The multicenter, open-label study is being carried out in the United Kingdom, Spain and Israel.

The study is comprised of two parts: (i) an accelerated dose-escalation part to assess the safety and tolerability of intratumorally injected AGI-134 as a monotherapy, as well as to determine the maximum tolerated dose and the recommended dose for part 2 of the study and (ii) a dose expansion part at the recommended dose, designed to assess the safety, tolerability and anti-tumor activity of AGI-134 as a monotherapy in a basket cohort of multiple solid tumor types. The first part of the study was completed in September 2019, with AGI-134 being found to be safe and well tolerated, with no serious drug-related adverse events or dose-limiting toxicities reported. The maximal tolerated dose was not reached and the recommended dose for the second part of the study was determined. We commenced the second part of the study in September 2019. Due to clinical operating issues associated with the COVID-19 pandemic, in April 2020, the clinical trial was temporarily suspended. In August 2020, we renewed study enrollment, and in January 2022, we completed enrollment. Initial proof-of-mechanism of action and efficacy results are expected in the second half of 2022.

In November 2018, the FDA granted the Biological Product Designation for AGI-134. This designation provides us with eligibility to obtain 12 years of market exclusivity upon approval of the product for commercial use by the FDA. This regulatory market exclusivity adds an incremental layer of protection in addition to that afforded by existing patents granted in the United States and Europe, and pending in other countries, covering the use of AGI-134 for the treatment of solid cancer tumors.

Commercialized Product

BL-5010

BL-5010 is a novel medical device containing an acidic, aqueous solution and applicator for the non-surgical removal of benign skin lesions. It offers an alternative to painful, invasive and expensive removal treatments including cryotherapy, laser treatment and surgery. Since the treatment is non-invasive, it poses minimal infection risk and eliminates the need for anesthesia, antiseptic precautions and bandaging. The pre-filled device controls and standardizes the volume of solution applied to a lesion, ensuring accurate administration directly on the lesion and preventing both accidental exposure of the healthy surrounding tissue and unintentional dripping. It has an ergonomic design, making it easy to handle, and has been designed with a childproof cap. BL-5010 is applied topically on a skin lesion in a treatment lasting a few minutes with the pen-like applicator and causes the lesion to gradually dry out and fall off within one to four weeks. We received European confirmation from British Standards Institute of the regulatory pathway classification of BL-5010 as a Class IIa medical device. We in-licensed the exclusive, worldwide rights to develop, market and sell BL-5010 from IPC in November 2007.

Development and Commercialization Arrangement. In December 2014, we entered into an exclusive out-licensing arrangement with Perrigo for the rights to BL-5010 for OTC indications in Europe, Australia and additional selected countries. We retain the OTC rights to BL-5010 in the United States and the rest of the world, as well as the non-OTC rights on a global basis. Under the original terms of our out-licensing arrangement with Perrigo, Perrigo was obligated to use commercially reasonable best efforts to obtain regulatory approval in the licensed territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications. In addition, Perrigo agreed to sponsor and manufacture BL-5010 in the relevant regions. Compensation by Perrigo for the exclusive license includes the payment to us of an agreed percentage of the gross revenue of sales of licensed products. We agreed to pay a portion of all net consideration we receive from Perrigo, within our standard range of sublicense receipt consideration, to IPC, the company from which we initially in-licensed the development rights to BL-5010. We have the right to prosecute and maintain the patents for BL-5010 in the licensed territories, and Perrigo agreed to bear the cost of all renewal fees for patents and the other costs of prosecution and maintenance up to an agreed limit. In addition, we were granted full access to all clinical and research and development data generated during the performance of the development plan and may use these data in order to develop or license the product in other territories and fields of use where we retain the rights. Our agreement with Perrigo will continue in effect until the cessation of all commercialization in the licensed territory. After the fifth anniversary of the first commercial sale of a licensed product, either party may terminate the agreement by giving at least 18 months' prior written notice to the other party. Either party may terminate the agreement (a) by providing 60 days' written notice of a material breach of the agreement by the other party if the breaching party does not cure the breach during that time or (b) with immediate effect on written notice to the other party if there is a change of control of the other party. The parties have agreed that the announced acquisition of Perrigo by Perrigo Company Plc is a change of control event that will not give rise to a right on our part to terminate the license agreement. In addition, we have the right to terminate the agreement if Perrigo does not fulfill any of its obligations of diligence with respect to launching a licensed product or obtaining regulatory approval for, and commercializing, licensed products as described above.

In March 2016, Perrigo received CE Mark approval for BL-5010 as a novel OTC treatment for the non-surgical removal of warts. The commercial launch of products for treatment of this first OTC indication (warts/verrucas) commenced in Europe in the second quarter of 2016. Since then, Perrigo has invested in improving the product and during 2019 launched an improved version of the product in several European countries.

In March 2020, we agreed that Perrigo could relinquish its license rights for certain countries that had been included in its territory according to the original license agreement and was also no longer obligated to develop, obtain regulatory approval for and commercialize products for a second OTC indication. In turn, in March 2020, we agreed with our licensor of the rights to BL-5010, IPC, to return to IPC those license rights no longer out-licensed to Perrigo as a result of the agreement described in the preceding sentence, in consideration of the payment to us of royalties or fees on sublicense receipts.

As a result of our out-licensing arrangement, as well as the previous discussions with other potential partners for this product, the commercialization activities for BL-5010 are currently focused on OTC indications. However, we may decide to seek collaboration partners for development of BL-5010 for non-OTC indications, or for OTC indications in territories not out-licensed to Perrigo, primarily the U.S.

Collaboration and Out-Licensing Agreements

Collaboration Agreement with MSD

See "—Therapeutic Candidates — Motixafortide — Clinical Trials — Solid tumors" for details regarding our collaboration with MSD.

Out-Licensing Agreement with Perrigo

See "—Commercialized Product— BL-5010— Development and Commercialization Arrangement" for details regarding our out-licensing agreement with Perrigo.

In-Licensing Agreements

We have in-licensed and intend to continue to in-license development, production and marketing rights from selected research and academic institutions in order to capitalize on the capabilities and technology developed by these entities. We also seek to obtain technologies that complement and expand our existing technology base by entering into license agreements with pharmaceutical and biotechnology companies. When entering into in-license agreements, we generally seek to obtain unrestricted sublicense rights consistent with our primarily partner-driven strategy. We are generally obligated under these agreements to diligently pursue product development, make development milestone payments, pay royalties on any product sales and make payments upon the grant of sublicense rights. We generally insist on the right to terminate any in-license for convenience upon prior written notice to the licensor.

The scope of payments we are required to make under our in-licensing agreements is comprised of various components that are paid commensurate with the progressive development and commercialization of our drug products.

Our in-licensing agreements generally provide for the following types of payments:

- Revenue sharing payments. These are payments to be made to licensors with respect to revenue we receive from sub-licensing to third parties for further development and commercialization of our drug products. These payments are generally fixed at a percentage of the total revenues we earn from these sublicenses.

- Milestone payments. These payments are generally linked to the successful achievement of milestones in the development and approval of drugs, such Phases 1, 2 and 3 of clinical trials and approvals of NDAs.

- Royalty payments. To the extent we elect to complete the development, licensing and marketing of a therapeutic candidate, we are generally required to pay our licensors royalties on the sales of the end drug product. These royalty payments are generally based on the net revenue from these sales. In certain instances, the rate of the royalty payments decreases upon the expiration of the drug's underlying patent and its transition into a generic drug. Certain of our agreements provide that if a licensed drug product is developed and sold through a different corporate entity, the licensors may elect to receive shares in such company instead of a portion of the royalties.

- Additional payments. In addition to the above payments, certain of our in-license agreements provide for a one-time or periodic payment that is not linked to milestones. Periodic payments may be paid until the commercialization of the product, either by direct sales or sublicenses to third parties. Other agreements provide for the continuation of these payments even following the commercialization of the licensed drug product.

The royalty and revenue-sharing rates we agree to pay in our in-licensing agreements vary from case to case but in most cases range from 20% to 29.5% of the consideration we receive from sublicensing the applicable therapeutic candidate. We are required to pay a substantially lower percentage, generally less than 5%, if we elect to commercialize the subject therapeutic candidate independently. Due to the relatively advanced stage of development of the compound licensed from Biokine, our license agreement with Biokine provides for royalty payments of 10% of net sales, subject to certain limitations, should we independently sell products. In addition, milestone payments are not generally payable if the revenue-sharing from an out-licensing transaction is greater than any relevant payments due under our in-licensing agreements.

The following are descriptions of our in-licensing agreements associated with our therapeutic candidates. In addition to the in-licensing agreements discussed herein, we have entered into other in-licensing arrangements in connection with our therapeutic candidates in clinical, advanced preclinical and feasibility stages.

Motixafortide

In September 2012, we in-licensed the rights to motixafortide under a license agreement with Biokine. Pursuant to the agreement, Biokine granted us an exclusive, worldwide, sublicensable license to develop, manufacture, market and sell certain technology relating to a short peptide that functions as a high-affinity antagonist for CXCR4 and the uses thereof.

There were no upfront payments due under the agreement. We are obligated to pay a monthly development fee of $27,500 for certain development services that Biokine has committed to provide to us under the agreement. The payment of this monthly fee will continue until the completion of the last clinical trial in which motixafortide is planned to be tested, or is being tested with, at least 20 subjects.

We are responsible for paying all development costs incurred by the parties in carrying out the development plan.

Should we independently develop manufacture and sell products (excluding sublicensing) containing the licensed technology, we are obligated to make royalty payments of 10% of net sales, subject to certain limitations.

The agreement also grants us the right to grant sublicenses for the licensed technology. Initially, we were required to pay Biokine a royalty payment of 40% of the amounts we receive as consideration in connection with any sublicensing, development, manufacture, marketing, distribution or sale of the licensed technology. In October 2018, Biokine agreed to reduce the royalty payment for sublicensing to 20% in return for the payment by us of $10 million in cash plus $5 million in our restricted shares. Biokine is also eligible to receive up to a total of $5 million in future milestone payments.

Before we in-licensed motixafortide, Biokine had received funding for the project from the IIA, and as a condition to IIA giving its consent to our in-licensing of motixafortide, we were required to agree to abide by any obligations resulting from such funding. However, if we become legally required to make payments to the IIA in respect of grants made to Biokine, we have the right to offset the full amount of such grants from any payments otherwise due to Biokine as sublicensing royalties as described above.

We are obligated under the agreement with Biokine to make commercially reasonable, good faith efforts to sublicense or commercialize motixafortide for fair consideration. If we do not fulfill this obligation within 24 months after completion of the development plan, all of the rights and responsibilities with respect to commercialization of the licensed technology will revert to Biokine, and our obligation to pay royalties for sales of any licensed products or sublicensing as described above will revert to Biokine.

We have the first right to prepare, file, prosecute and maintain any patent applications and patents, in respect of the licensed technology and any part thereof, at our expense, provided that we are required to consult with Biokine regarding patent prosecution and patent maintenance. In addition, we have the right to take action in the prosecution, prevention, or termination of any patent infringement of the licensed technology. We are responsible for all the expenses of any patent infringement suit that we bring, including any expenses incurred by Biokine in connection with such suits, with such expenses reimbursable from any sums recovered in such suit or in the settlement thereof for. After such reimbursement, if any funds remain, both we and Biokine are each entitled to a certain percentage of any remaining sums.

The agreement will remain in effect until the expiration of all of our royalty and sublicense revenue obligations to Biokine, determined on a product-by-product and country-by-country basis. We may terminate the agreement for any reason on 90 days' prior written notice to Biokine. Either party may terminate the agreement for a material breach by the other party if the breaching party is unable to cure the breach within 30 days after receiving written notice of the breach from the non-breaching party. With respect to any termination for a material breach, if the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, either party may terminate the agreement upon the occurrence of certain bankruptcy events.

Termination of the agreement will result in a loss of all of our rights to the drug and the licensed technology, which will revert to Biokine. In addition, any sublicense of ours will terminate provided that, upon such termination and at the request of the sublicensee, Biokine will be required to enter into a separate license agreement with the sublicensee on substantially the same terms as those contained in the applicable sublicense agreement.

AGI-134

Acquisition Agreements with Agalimmune

In March 2017, we acquired substantially all of the outstanding shares of Agalimmune and entered into the Agalimmune Development Agreement with the selling shareholders. We control the Agalimmune board of directors, and subject to the protections in favor of the selling shareholders, we will direct and be responsible for the planning, execution and day-to-day management of Agalimmune and its pipeline, including AGI-134.

The Agalimmune Development Agreement provides the selling shareholders with a reversionary option, in the event of a breach of that agreement and certain other limited triggering events, that permits the selling shareholders to re-acquire our equity interests in Agalimmune for nominal consideration. See "Risk Factors — Risks Related to Our Business Regulatory Matters — If we do not meet the requirements under our agreement with the Agalimmune selling shareholders, we could lose the rights to the therapeutic candidates in Agalimmune's pipeline, including but not limited to AGI-134."

License from the University of Massachusetts

In 2013, Agalimmune entered into an exclusive license agreement with the University of Massachusetts, which was amended and restated in February 2017, for rights to intellectual property related to AGI-134. Pursuant to the agreement, Agalimmune has an exclusive, worldwide, royalty-bearing, sublicensable license to develop, manufacture, use, import and sell licensed products. Agalimmune is obligated to use diligent efforts to develop the licensed products and to introduce them into the commercial market. The agreement sets forth specific development milestones that Agalimmune is required to fulfill. In consideration of the grant of the license, Agalimmune is obligated to pay upfront license fees, annual maintenance fees, milestone payments, and low, single digit royalty payments on the net sales of licensed products. In addition, the agreement provides that following a change of control event, Agalimmune will allot to the University 6% of its shares on a fully diluted basis. The agreement will remain in full effect until the later of expiration or abandonment of all valid claims in the licensed patents or 10 years from the date of first sale of a licensed product. Agalimmune may terminate the agreement for any reason on 90 days' prior written notice to the University.

License from Kode Biotech

In March 2015, Agalimmune entered into an evaluation license and option agreement with Kode Biotech for the rights to intellectual property related to certain water dispersible glycan-lipid conjugates (the "KODE™ Constructs"), including AGI-134. Pursuant to the agreement, Agalimmune had an exclusive license to pursue preclinical assessment of the use of the KODE™ Constructs in Agalimmune's method of promoting tumor anticancer therapy, and the exclusive right to require Kode Biotech to grant Agalimmune an exploitation license to pursue clinical development and commercialization of the use of the KODE™ Constructs in its method.

In September 2017, Agalimmune exercised its option to enter into the exploitation license agreement with Kode Biotech that grants Agalimmune a worldwide, exclusive, royalty-bearing transferable license to develop, manufacture, use, import and sell licensed products, including AGI-134. Agalimmune is obligated to use reasonable, diligent efforts to develop licensed products and to introduce licensed products into the commercial market. In consideration of the grant of the license, Agalimmune paid a license issue fee and is obligated to pay annual maintenance fees, milestone payments and low, single-digit royalty payments on the net sales of the licensed products. Agalimmune also has the right to grant sublicenses for the licensed technology and is required to pay Kode Biotech a payment based on the revenues from sublicense net sales. The agreement will remain in effect, unless terminated earlier in accordance with its terms, until the later of expiration or abandonment of all enforceable patent claims within the licensed patents.

BL-5010

In November 2007, we in-licensed the rights to develop and commercialize BL-5010 under a license agreement with IPC. Under the agreement, IPC granted us an exclusive, worldwide, sublicensable license to develop, manufacture, market and sell certain technology relating to an acid-based formulation for the non-surgical removal of skin lesions and the uses thereof. We are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan, including meeting certain specified diligence goals. We are required to make low, single-digit royalty payments on the net sales of the licensed technology if we manufacture and sell it on our own, subject to certain limitations. Our royalty payment obligations are payable on a product-by-product and country-by-country basis, until the last to expire of any patent included within the licensed technology in such country. We also have the right to grant sublicenses for the licensed technology and are required to pay IPC a payment, within our standard range of sublicense receipt consideration, based on the revenues we receive as consideration in connection with any sublicensing, development, manufacture, marketing, distribution or sale of the licensed technology.

The license agreement remains in effect until the expiration of all of our license, royalty and sublicense revenue obligations to IPC, determined on a product-by-product and country-by-country basis, unless we terminate the license agreement earlier. We may terminate the license agreement for any reason on 30 days' prior written notice. Either party may terminate the agreement for material breach if the breach is not cured within 30 days after written notice from the non-breaching party. If the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, either party may terminate the agreement upon the occurrence of certain bankruptcy events.

Termination of the agreement will result in a loss of all of our rights to the licensed technology, which would revert to IPC. In addition, any sublicense of the licensed technology will terminate provided that, upon termination, at the request of the sublicensee, IPC is required to enter into a license agreement with the sublicensee on substantially the same terms as those contained in the sublicense agreement.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our therapeutic candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. 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 trade secrets, know-how and continuing technological innovation, as well as on regulatory exclusivity, such as Orphan Drug designation or new chemical entity, or NCE, protection to develop and maintain our proprietary position.

Patents

As of March 15, 2022, we owned or exclusively licensed for uses within our field of business 32 patent families that collectively contain over 111 issued patents, two allowed patent applications and over 91 pending patent applications relating to the three candidates listed below. We are also pursuing patent protection for other drug candidates in our pipeline. Patents related to our therapeutic candidates may provide future competitive advantages by providing exclusivity related to the composition of matter, formulation, and method of administration of the applicable compounds and could materially improve the value of our therapeutic candidates. The patent positions for our three therapeutic candidates are described below and include both issued patents and pending patent applications we exclusively license. We vigorously defend our intellectual property to preserve our rights and gain the benefit of our investment.

- The motixafortide drug product candidate is covered as a composition of matter by a pending international patent application. Corresponding patents, if granted, will expire in December 2041, not including any applicable patent term extension, which may add an additional term of up to five years on the patent. We also have an exclusive license to a patent family that covers the active ingredient molecule per se. Patents of this family have been granted in the U.S., Europe, Japan and Canada. The patents will expire in August 2023, not including any applicable patent term extension. We have an exclusive license to a patent family that covers motixafortide combined with a PD1 antagonist for the treatment of cancer. A patent of this family has been granted in the U.S., and member patent applications are pending in Europe, Japan, China, Canada, Australia, India, Korea, Mexico, Brazil and Israel. The granted U.S. patent and patents to issue in the future based on pending patent applications in this family will expire in 2036, not including any applicable patent term extension. In addition, we have an exclusive license to nineteen other patent families pending or granted worldwide directed to methods of synthesis of motixafortide and methods of use of motixafortide either alone or in combination with other drugs for the treatment of certain types of cancer and other indications. Furthermore, we have Orphan Drug status for AML, pancreatic cancer and stem cell mobilization, as well as data exclusivity protection afforded to motixafortide as an NCE.

- With respect to AGI-134, Agalimmune owns or has an exclusive license to three patent families that cover the AGI-134 compound and its use for treating cancer. The use of AGI-134 for treating solid tumors is covered by patents granted in the U.S., Europe, China, Japan and other countries. The patents will expire in 2035, not including any applicable patent term extensions. The compound AGI-134 is covered by patents granted in the United States, Europe, Japan and other countries. The patents will expire in 2025, not including any applicable patent term extensions. In addition, the future drug product is eligible for obtaining regulatory Biological Product exclusivity (12 years of market exclusivity in the U.S.).

- With respect to BL-5010, we have an exclusive license to a patent family directed to a novel applicator uniquely configured for applying the BL-5010 composition to targeted skin tissue safely and effectively. Patents in this family have been granted in the U.S., Europe, Israel, Japan and China. The patents will expire in 2034.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, narrowed, circumvented or found to be invalid or unenforceable, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. Neither we nor our licensors can be certain that we were the first to invent the inventions claimed in our owned or licensed patents or patent applications. In addition, our competitors may independently develop similar technologies or duplicate any technology developed by us, and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Trade Secrets

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and assignment of invention agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, such agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Manufacturing

Our laboratories are located in our headquarters in Modi'in, Israel, and are in part compliant with FDA regulations setting forth current good laboratory practices, or GLP. While our bioanalytical laboratory complies with these regulations, the chemistry and formulation, as well as the analytical laboratories, are limited in manufacturing scale and resources and are intended to support our projects for research and development activities only. These laboratories are not compliant with cGMP. Hence, we cannot independently manufacture drug substances or drug products for our current clinical trials or for commercial distribution. The cGMP contract manufacturing organization of the drug substances and drug products used for our current clinical trials do have these necessary cGMP approvals.

There can be no assurance that our therapeutic candidates, if approved, can be manufactured in sufficient commercial quantities, in compliance with regulatory requirements, and at an acceptable cost. Our contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. Our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with cGMP on an ongoing basis, mandated by the FDA and other regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers.

Contract Research Organizations

We outsource certain preclinical and clinical development activities to CROs, which meet FDA or European Medicines Agency regulatory standards. We create and implement the drug development plans and, during the preclinical and clinical Phases of development, manage the CROs according to the specific requirements of the therapeutic candidate under development.

Competition

The pharmaceutical, medical device and biotechnology industries are intensely competitive. Our therapeutic candidates, if commercialized, would compete with existing drugs and therapies. In addition, there are many pharmaceutical companies, biotechnology companies, medical device companies, public and private universities, government agencies and research organizations actively engaged in research and development of products targeting the same markets as our therapeutic candidates. Many of these organizations have substantially greater financial, technical, manufacturing and marketing resources than we do. In certain cases, our competitors may also be able to use alternative technologies that do not infringe upon our patents to formulate the active materials in our therapeutic candidates. They may, therefore, bring to market products that are able to compete with our candidates, or other products that we may develop in the future.

Motixafortide

There are a number of potentially competitive compounds under development that act as CXCR4 inhibitors, including, among others, Mozobil® (plerixafor), which is being marketed by Sanofi Genzyme as a stem cell mobilizer for autologous stem cell transplantation; burixafor developed by GPCR Therapeutics; X4P-001 (mavorixafor) developed by X4 Pharmaceuticals Inc for WHIM syndrome; and GMI-1359 developed by Glyco-Mimetics Inc for Solid Tumors.

In the field of stem cell mobilization, in addition to the above-referenced Mozobil, MGTA-145 is a compound under development that could potentially be approved for stem cell mobilization in patients with genetic and autoimmune diseases Immuno-oncology is an area of great interest in the pharmaceutical market, specifically, immuno-oncology combination therapies. Currently there are hundreds of immuno-oncology combination treatments being tested in clinical trials that aim to transform scientific innovation into practice-changing cancer drugs.

In the field of pancreatic cancer, motixafortide, if approved, will compete with the few, currently approved treatments for PDAC. In the first line setting, Gemcitabine in combination with Abraxane® or FOLFIRINOX regimen are the current standard of care. Oncologists have limited options of existing therapies for second-line metastatic patients. The only FDA-approved second-line treatment is Onivyde® in combination with 5FU and LV for gemcitabine-treated patients. In addition to chemotherapy, Merck's KEYTRUDA® was approved for MSI-H cancers (approximately 1% of all cases) and Lynparza® was recently approved for maintenance of BRCA mutated pancreatic cancer (approximately 7% of all cases).

In the last years we have seen a number of late-stage clinical failures of compounds for advanced PDAC, most notably APX500, Eryspase and devimistat in the last year. Most of these failed trials have been based on a single promising endpoint. There are very few compounds in advanced stages of development in PDAC, most notably Noxxon's NOX-A12, which has announced initiation of a Phase 2 trial as a triple combination study in PDAC.

The field of AML has seen quite a few approvals in recent years, most of them being for specific subpopulations in specific lines of therapy. If approved, motixafortide will compete with many currently approved treatments for AML that include chemotherapy (doxorubicin, cytarabine, vincristine); radiation therapy; stem cell transplantation; hypomethylating agents Dacogen® (decitabine, Eisai and Johnson & Johnson); Vidaza® (azacitidine, Celgene); FLT3 Inhibitors Xospata® (gilteritinib), Vanflyta® (quizartinib); Rydapt® (midostaurin); IDH inhibitors Idhifa® (enasidenib) and Tibsovo® (ivosidenib). Other approved drugs for AML are Vyxeos® (liposomal cytarabine); Venclexta/Venclyxto® (Venetoclax, AbbVie); Daunorubicin® (Jazz Pharmaceuticals); Revlimid® (lenalidomide, Celgene); Daurismo® (glasdegib, Pfizer); and Mylotarg® (gemtuzumab, Pfizer).

In addition there are a number of potentially competitive compounds in development to treat AML including, among others, crenolanib (Arog Phramaceuticals), oral azacytidine (Celgene/Bristol Myers Squibb); guadecitabine (Astex Pharmaceuticals / Otsuka); uprolesan (Glycomimetics); pracinostat (MEI Pharma/Helsinn); devimistat (Rafael Pharmaceuticals); ibrutinib (AbbVie); enasidenib (Bristol Myers Squibb); alvocidib (Tolero Pharmaceuticals); daratumumab (Johnson & Johnson); brentuximab (Seattle Genetics); selinexor (Karyopharm Therapeutics and Ono Pharmaceutical Co Ltd.); Nexavar (sorafenib, Bayer).

AGI-134

The field of cancer immunotherapy is rapidly growing, targeting CTLA-4, PD1 or PDL1 via antibody blockade. In recent years, approval has been granted for use of these agents for various oncology-related indications such as melanoma, non-small cell lung cancer, renal cell carcinoma, head and neck, gastric and colorectal cancer, liver cancer and bladder cancer. As noted above, there are currently hundreds of immuno-oncology combination treatments being tested in clinical trials. Many of these combinations could be competitive with AGI-134.

In general, the competitive landscape is comprised of compounds that target tumor specific neoantigens and create adaptive, anti-tumor immune response. Examples of such therapeutic approaches include oncolytic viruses, dendritic cell vaccines, personalized neoantigen-based cancer vaccines, pathogen-associated molecular patterns (PAMPs), damage-associated molecular pattern (DAMPs) and cancer vaccines.

If approved, AGI-134 will compete with approved treatments such as the oncolytic viruses Imlygic® (T-VEC; Amgen) and dendritic cell cancer vaccine Provenge® (sipuleucel-T; Dendreon Corp). In addition, there are several potentially-competitive compounds that are currently under development, including, among others, Pexa-Vec (pexastimogene devacirepvec, SillaJen and Transgene); Reolysin (pelareorep, Adlai Nortye Pharmaceutical Co Ltd and Oncolytics Biotech Inc.); Cavatak (MSD/Viralytics); NeoVax (BioNTech/Neon Therapeutics); IVAC Mutanome (BioNTech); TLR9 agonists such as lefitolimod (MGN-1703, Mologen Ag); tilsotolimod (IMO-2125, Idera Pharmaceuticals Inc.); SD-101 (TriSalus Life Sciences); CMP-001 (Checkmate Pharmaceuticals); ADU-S100 (Aduro BioTech Inc./Novartis); imprime PGG® (HiberCell) and MG1MA3 (Turnstone Biologics Inc/AbbVie). Most of these competitors have ongoing combination trials with the approved checkpoint inhibitors.

BL-5010

BL-5010 competes with a variety of approved destructive and non-destructive treatments for skin lesions. Both Endwarts® (Meda Health) and Eskata® (Aclaris therapeutics) are medical device-based treatments marketed for removal of warts.

Insurance

We maintain insurance for our offices and laboratory in Israel. This insurance covers approximately $5.3 million of equipment, consumables and lease improvements against risk of fire, lightning, natural perils and burglary (the latter coverage limited to $250,000), and $1.5 million of consequential damages (covering fixed damages and extra expenses). For our clinical activities, we carry life science liability insurance covering general liability with an annual coverage amount of $30.0 million per occurrence and product liability and clinical trials coverage with an annual coverage amount of $30.0 million each claim and in the aggregate. The annual aggregate as well as the maximum indemnity for a single occurrence, claim or circumstances under this insurance is $30.0 million. In addition, we maintain the following insurance: employer's liability with coverage of $10.0 million for each occurrence and in the aggregate; third-party liability with coverage of $5.0 million for each occurrence and in the aggregate; all risk coverage of approximately $2.6 million for electronic and mechanical equipment; directors' and officers' liability with coverage of $15.0 million for each claim and in the aggregate; stock throughput insurance covering the API, clinical trials materials; and a global travel insurance policy.

We procure stock throughput insurance (cargo marine) coverage when we ship substances for our clinical studies. Such insurance is customized to the special requirements of the applicable shipment, such as temperature and/or climate sensitivity. If required, we insure the substances to the extent they are stored in central depots and at clinical sites.

We believe that the amounts of our insurance policies are adequate and customary for a business of our kind. However, because of the nature of our business, we cannot assure you that we will be able to maintain insurance on a commercially reasonable basis or at all, or that any future claims will not exceed our insurance coverage.

Environmental Matters

We are subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. We believe that our business, operations and facilities are being operated in compliance in all material respects with applicable environmental and health and safety laws and regulations. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on us. The operation of our facilities, however, entails risks in these areas. Significant expenditures could be required in the future if we are required to comply with new or more stringent environmental or health and safety laws, regulations or requirements. See "Business — Government Regulation and Funding — Israel Ministry of Environment — Toxin Permit."

Government Regulation and Funding

We operate in a highly controlled regulatory environment. Stringent regulations establish requirements relating to analytical, toxicological and clinical standards and protocols in respect of the testing of pharmaceuticals and medical devices. Regulations also cover research, development, manufacturing and reporting procedures, both pre- and post-approval. In many markets, especially in Europe, marketing and pricing strategies are subject to national legislation or administrative practices that include requirements to demonstrate not only the quality, safety and efficacy of a new product, but also its cost-effectiveness relating to other treatment options. Failure to comply with regulations can result in stringent sanctions, including product recalls, withdrawal of approvals, seizure of products and criminal prosecution.

Before obtaining regulatory approvals for the commercial sale of our therapeutic candidates, we or our licensees must demonstrate through preclinical studies and clinical trials that our therapeutic candidates are safe and effective. Historically, the results from nonclinical studies and early clinical trials often have not accurately predicted results of later clinical trials. In addition, a number of pharmaceutical products have shown promising results in early clinical trials but subsequently failed to establish sufficient safety and efficacy results to obtain necessary regulatory approvals. We have incurred and will continue to incur substantial expense for, and devote a significant amount of time to, preclinical studies and clinical trials. Many factors can delay the commencement and rate of completion of clinical trials, including the inability to recruit patients at the expected rate, the inability to follow patients adequately after treatment, the failure to manufacture sufficient quantities of materials used for clinical trials, and the emergence of unforeseen safety issues and governmental and regulatory delays. If a therapeutic candidate fails to demonstrate safety and efficacy in clinical trials, this failure may delay development of other therapeutic candidates and hinder our ability to conduct related preclinical studies and clinical trials. Additionally, as a result of these failures, we may also be unable to find additional licensees or obtain additional financing.

Governmental authorities in all major markets require that a new pharmaceutical product or medical device be approved or exempted from approval before it is marketed, and have established high standards for technical appraisal, which can result in an expensive and lengthy approval process. The time to obtain approval varies by country. In the past, it generally took from six months to four years from the application date, depending upon the quality of the results produced, the degree of control exercised by the regulatory authority, the efficiency of the review procedure and the nature of the product. Some products are never approved. In recent years, there has been a trend towards shorter regulatory review times in the United States as well as certain European countries, despite increased regulation and higher quality, safety and efficacy standards.

Historically, different requirements by different countries' regulatory authorities have influenced the submission of applications. However, a trend toward harmonization of drug and medical device approval standards, starting in individual countries in Europe and then in the EU as a whole, in Japan, the United Kingdom and in the United States under the aegis of what is now known as the International Council on Harmonisation, or ICH (created as the International Conference on Harmonisation in 1990), is gradually narrowing these differences. In many cases, compliance with ICH standards can help avoid duplication of non-clinical and clinical trials and enable companies to use the same basis for submissions to each of the respective regulatory authorities. The adoption of the Common Technical Document format by the ICH has greatly facilitated use of a single regulatory submission for seeking approval in the ICH regions and many other countries worldwide.

Summaries of the United States, EU, United Kingdom and Israeli regulatory processes follow below.

United States

In the United States, drugs are subject to rigorous regulation by the FDA. The U.S. Federal Food, Drug and Cosmetic Act, or FDCA, and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, record-keeping, packaging, labeling, adverse event reporting, advertising, promotion, marketing, distribution and import and export of pharmaceutical products. Failure to comply with the applicable U.S. requirements may subject us to stringent administrative or judicial sanctions, such as agency refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions or criminal prosecution.

Unless a drug is exempt from the NDA process or the Biologics License Application, or BLA, process or subject to another regulatory procedure, the steps required before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation development;
- submission to the FDA of an Investigational New Drug, or IND, application to conduct human clinical testing;
- adequate and well controlled clinical trials to determine the safety and efficacy of the drug for each indication as well as to establish the exposure levels;
- submission to the FDA of an application for marketing approval;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is manufactured; and
- FDA review and approval of the drug and drug labeling for marketing.

Preclinical studies include laboratory evaluation of product chemistry, toxicity, formulation and stability, as well as animal studies. For preclinical studies conducted in the United States, and certain studies carried out outside the United States, we submit the results of the nonclinical studies, together with manufacturing information and analytical results, to the FDA as part of an IND, which must become effective before we may commence human clinical trials.

Clinical Trials (INDs)

Clinical trials involve the administration of the investigational drug to people under the supervision of qualified investigators in accordance with the principles of good clinical practice, or GCP. We conduct clinical trials under protocols detailing the trial objectives, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. We must submit each U.S. study protocol to the FDA as part of an IND. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND does not always result in the FDA allowing clinical trials to commence and the FDA may halt a clinical trial if unexpected safety issues surface or the study is not being conducted in compliance with applicable requirements.

The FDA may refuse to accept an IND for review if applicable regulatory requirements are not met. Moreover, the FDA may delay or prevent the start of clinical trials if the manufacturing of the study drug fails to meet cGMP requirements or the clinical trials are not adequately designed. Such government regulation may delay or prevent the study and marketing of potential products for a considerable time period and may impose costly procedures upon a manufacturer's activities. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot continue without FDA authorization and then only under terms authorized by the FDA.

Success in early-stage clinical trials does not assure success in later-stage clinical trials. Results obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a therapeutic candidate receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or even withdrawal of marketing approval for the product.

Foreign clinical trials may or may not be conducted under an IND. However, their safety assessments should be submitted annually.

We conduct clinical trials typically in three sequential phases (1-3), but the phases may overlap or be combined. An institutional review board, or IRB, must review and approve each trial before it can begin. Phase 1 includes the initial administration of a tested drug to a small number of humans. These trials are closely monitored and may be conducted in patients but are usually conducted in healthy volunteer subjects. These trials are designed to determine the metabolic and pharmacologic actions of the drug in humans and the side effects associated with increasing doses as well as, if possible, to gain early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks and preliminarily evaluate the efficacy of the drug for specific indications. Phase 3 trials are large trials used to further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There can be no assurance that we or our licensees will successfully complete Phase 1, Phase 2 or Phase 3 testing with respect to any therapeutic candidate within any specified period of time, if at all. Furthermore, clinical trials may be suspended at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. We and our licensees perform some of our nonclinical and clinical testing outside of the United States. The acceptability of the results of our preclinical and clinical testing by the FDA will be dependent upon adherence to applicable U.S. and foreign standards and requirements, including GLP, GCP and the Declaration of Helsinki for protection of human subjects.

Marketing Applications (NDAs and BLAs)

After successful completion of the required clinical testing, an NDA, or in the case of certain biological products a BLA, is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before product marketing may begin in the United States. The NDA/BLA must include the preclinical and clinical testing results and a compilation of detailed information relating to the product's pharmacology, toxicology, chemistry, manufacture and manufacturing controls. The cost of preparing and submitting an NDA may be substantial. Under U.S. federal law, the submission of NDAs is generally subject to substantial application user fees, and the manufacturer and/or sponsor under an NDA approved by the FDA is also subject to annual product and establishment user fees. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA/BLA to determine whether the application will be accepted for filing based on the FDA threshold determination that the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the submitted application. Under U.S. federal law, the FDA has agreed to certain performance goals in the review of NDAs/BLAs. Most such applications for non-priority drug products are to be reviewed within 10 months. The review process may be significantly extended by FDA requests for additional information or clarification or if the applicant submits a major amendment during the review. The FDA may also refer applications to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. This often, but not exclusively, occurs for novel drug products or drug products that present difficult questions of safety or efficacy. The FDA is not bound by the recommendation of an advisory committee.

Before approving an application, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve the application unless the FDA determines that the product is manufactured in substantial compliance with GMP. If the FDA determines that the NDA or BLA is supported by adequate data and information, the FDA may issue an approval letter. During review, the FDA may request additional information via an information request, or IR letter, or state deficiencies via a deficiency letter, or DR letter. Upon compliance with the conditions stated, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of approval, the FDA may require additional trials or post-approval testing and surveillance to monitor the drug's safety or efficacy, the adoption of risk evaluation and mitigation strategies, and may impose other conditions, including labeling and marketing restrictions on the use of the drug, which can materially affect its potential market and profitability. Once granted, product approvals may be withdrawn if compliance with regulatory standards for manufacturing and quality control are not maintained or if additional safety problems are identified following initial marketing.

If the FDA's evaluation of the NDA or BLA submission or manufacturing processes and facilities is not favorable, the FDA may refuse to approve the NDA or BLA and may issue a complete response letter. The complete response letter, or CRL, indicates that the review cycle for an application is complete and that the application is not ready for approval. The complete response letter will describe specific deficiencies and, when possible, will outline recommended actions the applicant might take in order to place the application in condition for approval. Following receipt of a CRL, the company may submit additional information and start a new review cycle, withdraw the application or request a hearing. Failure to take any of the above actions may result in the FDA considering the application withdrawn following one year from issuance of the CRL. In such cases, the FDA will notify the company and the company will have 30 days to respond and request an extension of time in which to resubmit the application. The FDA may grant reasonable requests for extension. If the company does not respond within 30 days of the FDA's notification, the application will be considered withdrawn. Even with submission of additional information for a new review cycle, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The Pediatric Research Equity Act, or PREA, requires NDAs and BLAs (or supplements) for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to contain results assessing the safety and efficacy for the claimed indication in all relevant pediatric subpopulations. Data to support dosing and administration also must be provided for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for the submission of results or full or partial waivers from the PREA requirements (for example, if the product is ready for approval in adults before pediatric studies are complete, if additional safety data is needed, among others). In addition, under the Best Pharmaceuticals for Children Act, or BPCA, the FDA may issue a written request to the company to conduct clinical trials in the pediatric population that are related to the moiety and expand on the claimed indication. The studies are voluntary but may award the company with 6 months of marketing exclusivity if conducted according to good scientific principles and address the written request. Finally, a sponsor can request that a product that must be studied under PREA to be studied also under the BPCA to allow the sponsor to be eligible for six-months of pediatric exclusivity. The pediatric studies requested under BPCA are usually more extensive and would generally also fulfill the PREA requirement; however, even if the sponsor does not complete the studies outlined in the BPCA written request, it is still required to complete any studies required under PREA.

Post-Marketing Requirements

Once an NDA or BLA is approved, the drug sponsor will be subject to certain post-approval requirements, including requirements for adverse event reporting, submission of periodic reports, manufacturing, labeling, packaging, advertising, promotion, distribution, record-keeping and other requirements. For example, the approval may be subject to limitations on the uses for which the product may be marketed or conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product or require the adoption of risk evaluation and mitigation strategies. In addition, the FDA requires the reporting of any adverse effects observed after the approval or marketing of a therapeutic candidate and such events could result in limitations on the use of such approved product or its withdrawal from the marketplace. Also, some types of changes to the approved product, such as manufacturing changes and labeling claims, are subject to further FDA review and approval. Additionally, the FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, the FDA requires substantiation of any claims of superiority of one product over another including, in many cases, requirements that such claims be proven by adequate and well controlled head-to-head clinical trials. To the extent that market acceptance of our therapeutic candidates may depend on their superiority over existing products, any restriction on our ability to advertise or otherwise promote claims of superiority, or any requirements to conduct additional expensive clinical trials to provide proof of such claims, could negatively affect the sales of our therapeutic candidates and our costs.

Orphan Drug Designation

The Orphan Drug Act, or ODA, provides for granting special status to a drug or biological product to treat a rare disease or condition (i.e., a disease or condition that affects fewer than 200,000 individuals in the United States) upon request of a sponsor. This status is referred to as orphan designation (or sometimes "orphan status"). For a therapeutic candidate to qualify for orphan designation, both the candidate and the disease or condition must meet certain criteria specified in the ODA's implementing regulations (set forth at 21 CFR Part 316). Orphan designation qualifies the sponsor of the candidate for various development incentives of the ODA, including tax credits for qualified clinical testing, waiver of NDA/BLA user fees and eligibility for seven-year marketing exclusivity, referred to as orphan exclusivity upon marketing approval. The granting of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and effectiveness of a candidate must still be established through adequate and well-controlled studies.

Expedited Programs for Serious Conditions

The FDA has put in place four programs intended to facilitate and expedite development and review of a new drug intended to address an unmet medical need in the treatment of a serious or life-threatening condition: fast track designation, breakthrough therapy designation, accelerated approval and priority review designation. Each program offers the sponsor a defined set of opportunities such as expedited development and review, intensive FDA guidance during development, marketing approval based on an effect on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict the drug's clinical benefit, and a shorter time for review of marketing application. Fast Track and Breakthrough Therapy designations may be requested during development, while Accelerated Approval and Priority Review relate to the marketing approval stage.

European Union/European Economic Area

Clinical Trials

Within the European Union (EU) and the European Economic Area (EEA), which is composed of the 27 member states of the EU plus Norway, Iceland and Liechtenstein, the authorization of clinical trials occurs at member state level. The European Medicines Agency, or EMA, plays a key role in ensuring that GCP standards are applied across the European Economic Area, or EEA in cooperation with the member states. It also manages a database of clinical trials carried out in the EU.

Clinical trials in the EU are now regulated under Regulation (EU) 536/2014, or the CTR. As opposed to the former law, Directive 2001/20/EC, or CTD, which as an EU directive was not directly applicable in the member states, the CTR has immediate effect and does not have to be transposed into national law. While national law transposing the CTD varied to a great extent, the CTR aims at significant further harmonization of the law governing clinical trials in the EU. After significant delay, the CTR has now become applicable on January 31, 2022. The CTR further harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, or CTIS, which includes a centralized EU portal and database for clinical trials. The exact timing of the Regulation's application depends on confirmation of full functionality of CTIS through an independent audit. The CTR will become applicable six months after the European Commission publishes notice of this confirmation. The CTR provides inter alia:

- Consistent rules for conducting clinical trials throughout the EU;
- Making information on the authorization, conduct and results of each clinical trial carried out in the EU publicly available;

- Harmonized electronic submission and assessment process for clinical trials conducted in multiple member states;
- Improved collaboration, information sharing and decision-making between and within member states;
- Increased transparency of information on clinical trials; and
- Higher standards of safety for all participants in EU clinical trials.

The authorization of a clinical trial (Phase I-III) in an EU member state requires the submission of a clinical trial application (CTA) via the EU Portal. The application will be reviewed by the competent authorities of the member states where the trial is supposed to take place. The application and approval process is conducted by the member states under the cooperation system set forth in the CTR. Particularities under member states' national law still apply to some extent. In general, the CTA should include, among other documents, the study protocol, results of the nonclinical studies and manufacturing information and analytical results. Also, the sponsor has to suggest one of the concerned member states as reporting member state. The CTR aims at speeding up the validation and review of clinical trial applications and therefore provides strict deadlines.

Marketing Authorization Procedures

A medicinal product may only be placed on the market in the EEA if it has obtained a marketing authorization according to the applicable EU and/or member state law. A marketing authorization may either be granted in a national procedure, or in a coordinated procedure of several member states pursuant to Directive 2001/83/EC, as amended, or under the centralized EU procedure in accordance with Regulation (EC) No. 726/2004, as amended, or its predecessor, Regulation 2309/93. Depending on the nature of the medicinal product, several different legal frameworks of the EU and the member states may be relevant for the market clearance.

Centralized Procedure (CP)

The Centralized Procedure according to Regulation 726/2004/EC allows a marketing authorization holder to market the medicine and make it available to patients and healthcare professionals throughout the entire EEA on the basis of a single marketing authorization, granted by the European Commission, acting in its capacity as the European Licensing Authority on the advice of the EMA. The EMA is the administrative body responsible for coordinating the existing scientific resources available in the member states for evaluation, supervision and pharmacovigilance of medicinal products. Certain medicinal products (e.g., products derived from biotechnology, orphan medicinal products and medicinal products for human use, which contain an active substance authorized in the Union after 20 May 2004 and which are intended for the treatment of AIDS, cancer, neurodegenerative disorders or diabetes) must be authorized centrally. For each application submitted to the EMA for scientific assessment, the EMA is required to ensure that the opinion of the Committee for Medicinal Products for Human Use, or CHMP, is given within 210 days after receipt of a valid application or within 150 days by means of an accelerated procedure (excluding clock stops); the review period can be extended. If the opinion is positive, the EMA is required to send the opinion to the European Commission, which is responsible for preparing the decision granting a marketing authorization. If the initial opinion of the CHMP is negative, the applicant is afforded an opportunity to seek a re-examination of the opinion. The CHMP is required to re-examine its opinion within 60 days following receipt of the request by the applicant. A refusal of a centralized marketing authorization constitutes a prohibition on placing the given medicinal product on the market in the EU.

The EMA's Committee for Advanced Therapies (CAT) is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products (ATMP). ATMP include gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for an ATMP candidate that is submitted to the EMA. The EMA then provides a final opinion regarding the application for marketing authorization. The European Commission grants or refuses marketing authorization after the EMA has delivered its opinion. ATMP are further regulated under Regulation (EC) No 1394/2007 on advanced therapy medicinal products.

National Authorization Procedure

A National Authorization Procedure is used when applying for a marketing authorization in one individual EEA state. The national procedure can only be used if the medicinal product does not already have a marketing authorization in another EEA state.

Mutual Recognition Procedure (MRP)

The mutual recognition procedure (Art. 28 et seq. Directive 2001/83/EC) should be used if a medicinal product already has a marketing authorization in one EEA member state, and the authorization holder would like to extend the authorization to other member states. An application for mutual recognition may be addressed to one or more EEA countries. The country in which the national marketing authorization has been granted acts as the Reference Member State, and the other countries concerned (Concerned Member States) can, upon successful completion of the procedure, recognize the marketing authorization. The assessment time is 180 days plus 30 days.

Decentralized Procedure (DCP)

The decentralized procedure (introduced by Directive 2004/27/EU) is used in cases where the medicinal product has not received a marketing authorization in the EU at the time of application. It allows the common assessment of an application submitted simultaneously to several member states. One of the member states will take the lead in evaluating the application as Reference Member State. The Reference Member State should prepare an assessment report that is then used to facilitate agreement with the Concerned Member States and the grant of a national marketing authorization in all of these member states. The assessment time is 210 days + 30 days.

Manufacturing Requirements

Any medicinal product placed on the market in the EEA must be manufactured in accordance with the principles of good manufacturing practice as set out in Directive 2003/94/EC for medicines and investigational medicines for human use and Volume 4 of the "Rules Governing Medicinal Products in the European Community" or Directive 2017/1572/EU that will replace Directive 2003/94/EC once the notice according Art. 82(3) CTR has been filed. Furthermore, distribution of medicinal products in the EU is subject to Directive 2001/83/EC, 92/25/EEC and current guidance on good distribution practice, or GDP. Moreover, EU law requires the clinical results in support of clinical safety and efficacy to be based upon clinical trials conducted in the EU in compliance with the requirements of Directives 2001/20/EC and 2005/28/EC, which implement good clinical practice in the conduct of clinical trials on medicinal products for human use. Clinical trials conducted outside the EU and used to support applications for marketing within the EU must have been conducted in a way consistent with the principles set out in Directive 2001/20/EC. The conduct of a clinical trial in the EU requires, pursuant to Directive 2001/20/EC, authorization by the relevant national competent authority where a trial takes place, and an ethics committee to have issued a favorable opinion in relation to the arrangements for the trial. It also requires that the sponsor of the trial, or a person authorized to act on his behalf in relation to the trial, be established in the EU. As stated above, directive 2001/20/EC will be replaced by the CTR in the future, however, the exact time of the replacement is still uncertain.

Law Relating to Pediatric Research

Regulation (EC) 1901/2006 (as amended by Regulation (EC) 1902/2006 and Regulation (EU) 2019/5), or the Pediatric Regulation, was adopted on December 12, 2006. This Regulation governs the development of medicinal products for human use in order to meet the specific therapeutic needs of the pediatric population (children aged 0 to 17 years). It requires any application for marketing authorization made after July 26, 2008 in respect of a medicinal product not authorized in the EU on January 26, 2007, the time the Regulation entered into force, to include studies in children conducted in accordance with a pediatric investigation plan agreed to by the relevant European authorities. This does not apply if the product is subject to an agreed waiver or deferral or if the product is excluded from the scope of Regulation 1901/2006, which is the case for *inter alia* generics, homeopathic and traditional (herbal) medicinal products. Waivers can be granted in certain circumstances where pediatric studies are not required or desirable. Deferrals can be granted in certain circumstances where the initiation or completion of pediatric studies should be deferred until appropriate studies in adults have been performed. Moreover, this regulation imposes the same obligation from January 26, 2009 on an applicant seeking approval of a new indication, pharmaceutical form or route of administration for a product already authorized and still protected by a supplementary protection certificate granted under Regulation (EC) no. 469/2009 or its precursor Regulation (EEC) 1768/92 by a patent that qualifies for the granting of such a supplementary protection certificate. The pediatric Regulation 1901/2006 also provides, subject to certain conditions, a reward for performing such pediatric studies, regardless of whether the pediatric results provided resulted in the grant of a pediatric indication. This reward comes in the form of an extension of six months to the supplementary protection certificate granted in respect of the product, unless the product is subject to Orphan Drug designation, in which case the 10-year market exclusivity period for such orphan products is extended to 12 years. If any of the non-centralized procedures for marketing authorization have been used, the six-month extension of the supplementary protection certificate is only granted if the medicinal product is authorized in all member states. Where the product is no longer covered by a patent or supplementary protection certificate, the applicant may make a separate application for a Pediatric Use Marketing Authorization, or PUMA, which, on approval, will provide eight years' protection for data and 10 years' marketing protection for the pediatric results.

Post-authorization Obligations

An authorization to market a medicinal product in the EU carries with it an obligation to comply with many post-authorization regulations relating to the marketing and other activities of authorization holders. These include requirements relating to provision of a risk management plan and provision of annual periodic safety update reports, carrying out of post-authorization efficacy studies and/or post-authorization safety studies, maintenance of a pharmacovigilance system master file, adverse event reporting, signal detection and management and other pharmacovigilance activities conducted under an established quality system, advertising, packaging and labelling, patient package leaflets, and distribution. The regulations frequently operate within a criminal law framework, and failure to comply with the requirements may not only affect the authorization, but also can lead to financial and other sanctions levied on the company in question and responsible officers. EU pharmacovigilance legislation has been significantly modified by the Pharmacovigilance Directive, Directive 2010/84/EU which amended the legal framework of pharmacovigilance for medicines marketed within the EU provided in Regulation (EC) No 726/2004 with respect to EU authorized medicinal products and in Directive 2001/83/EC with respect to nationally authorized medicinal products (including those authorized through the mutual recognition and decentralized systems). Furthermore, EU good pharmacovigilance practice (GVP) rules apply. With the amended pharmacovigilance requirements, the financial and organizational burden on market authorization holders increased significantly, such as the obligation to maintain a pharmacovigilance system master file that applies to all holders of marketing authorizations granted in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004. Marketing authorization holders must furthermore collect data on adverse events associated with use of the authorized product outside the scope of the authorization. Pharmacovigilance for biological products and medicines with a new active substance is strengthened by subjecting their authorization to additional monitoring activities.

Another relevant aspect in the EU regulatory framework is the “sunset clause”: a provision leading to the cessation of the validity of any marketing authorization if it is not followed by marketing within three years or, if marketing is interrupted for a period of three consecutive years.

Approval of Medical Devices

On May 26, 2021 the new Regulation EU No. 2017/745 on Medical Devices (Medical Devices Regulation) became applicable and has replaced the former regulatory framework for medical devices in the EU. The Medical Devices Regulation strengthens the medical devices rules in the EU. In particular, the Medical Devices Regulation results in several medical devices being classified in higher risk classes and therefore face elevated regulatory requirements. In addition, the Medical Devices Regulation generally elevates regulatory requirements to medical devices. With regard to in vitro diagnostic medical devices, the new Regulation EU 746/2017 on in vitro diagnostic medical devices will replace the current legal framework on May 26, 2022 and will also result in a stricter regime.

As the previous regime, the MDR requires that manufacturers of medical devices obtain the right to affix the CE mark to their products, which shows that the device has undergone a conformity assessment procedure, before selling them in EU member countries. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European law. In order to obtain the right to affix the CE mark to products, a manufacturer has to conduct the applicable conformity assessment procedure that may include a certification process involving a notified body. The type of conformity procedure that is applicable varies according to the nature of the device. Once the procedure has been successfully completed, the manufacturer is entitled to affix the CE mark on its products and commercially distribute those products throughout the EU without further conformance tests being required in other member states.

Data Privacy in the EU

The EU has a strict regime on data privacy under the General Regulation on Data Protection, Regulation 2016/679 (GDPR) that has become applicable on May 25, 2018. The GDPR as an EU regulation does not have to be implemented into member states' national law but applies directly in all member states. It applies to companies with an establishment in the European Economic Area (EEA) that includes the 27 member states of the EU and Norway, Iceland and Liechtenstein. Furthermore, the GDPR applies to companies not located in the EEA but processing personal data of individuals located in the EEA (e.g., through online business). The GDPR implements stringent operational requirements for controllers of personal data, including, for example, obligations to justify the collection, use and other processing of personal data (e.g., based on the individual's consent), to notify the individuals concerned about data processing activities, to protect all processed personal data through appropriate technical and organizational measures, and to implement a data protection compliance management. Furthermore, the GDPR defines high data security and compliance standards for the transfer of personal data to third countries, including the U.S. The operational requirements under the GDPR are even stricter in case of sensitive personal data, such as health or genetic data, that typically have to be stored in a pseudonymized (i.e., key-coded) manner. The GDPR provides that EU member states may in certain areas deviate from GDPR standards which results in varying laws and regulations at member states level. The applicable data protection laws in the EEA may limit our ability to share and otherwise process personal data. If our business falls below the GDPR standards, we may be subject to severe administrative fines (under the GDPR, in the amount of up to 4 % of the total worldwide annual turnover of our preceding financial year) and suffer significant loss of reputation.

United Kingdom

Effect of Brexit and Changed Legislation

The withdrawal of the United Kingdom (UK) from the EU took effect on January 1, 2021 (Brexit), and there are 27 member states remaining in the EU. As of January 1, 2021, the UK is a "third country" with regard to the EU (subject to the terms of the EU UK Trade Agreement) and EU law ceased to apply directly in the UK. However, the UK has retained the EU regulatory regime as standalone UK legislation with some amendments to reflect procedural and other requirements with respect to marketing authorizations and other regulatory provisions. Therefore, the UK regulatory regime with respect to medicines and medical devices is currently similar to EU regulations, but under new legislation, the Medicines and Medical Devices Act 2021, the UK may adopt changed regulations that may diverge from the EU legislative regime for medicines and their research, development and commercialization, medical devices and clinical trials. The separate UK regulatory system for these areas, albeit with transitional recognition procedures in the UK, may lead to additional regulatory costs.

In order to market a medicinal product in the United Kingdom, a license or marketing authorization must be obtained from the United Kingdom Medicines and Healthcare Products Regulatory Agency, or MHRA. The United Kingdom legislation includes multiple assessment routes for applications for medicinal products, including a 150-day national assessment or a rolling review application. Further, and for a transitional period until 31 December 2022, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure. In addition, the MHRA has the power to have regard to marketing authorizations approved in EU member states.

The MHRA reviews applications for orphan designation at the time of a marketing authorization application or as part of a subsequent variation to that authorization. To qualify for orphan designation, a medicine must meet certain criteria in the United Kingdom including that the medicine for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating, the prevalence of the condition must not be more than 5 in 10,000 or it must be unlikely that the marketing would generate sufficient returns to justify investment and no satisfactory method of diagnosis, prevention or treatment must exist in Great Britain or, if such a method exists the medicine must be of significant benefit to those affected by the condition. On grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication starting from the date of first approval of the product in Great Britain.

The United Kingdom has adopted new legislation, the Medicines and Medical Devices Act 2021 and may make changes to the licensing or authorization of medicines in the future.

Clinical Trials

As a consequence of Brexit, the United Kingdom has not adopted the new EU Regulation on Clinical Trials (Reg. EU No. 536/2014), or CTR, that became applicable on 31 January 2022. The rules with respect to clinical trials in the United Kingdom are therefore different from those in the EU and are based on previous EU legislation. In January 2022, the United Kingdom issued a consultation with respect to changes to clinical trial legislation.

Data Privacy in the EU

The UK's data protection regime is currently based on the GDPR which continues to form part of law in the United Kingdom with some amendments following Brexit although there is a risk of divergence in the future which may increase our overall data protection compliance cost.

Israel

Israel Ministry of the Environment — Toxin Permit

In accordance with the Israeli Dangerous Substances Law - 1993, the Israeli Ministry of the Environment is required to grant a permit in order to use toxic materials. Because we utilize toxic materials in the course of operation of our laboratories, we were required to apply for a permit to use these materials. Our current toxin permit will remain in effect until February 2025.

Clinical Testing in Israel

In order to conduct clinical testing on humans in Israel, special authorization must first be obtained from the ethics committee and general manager of the institution in which the clinical studies are scheduled to be conducted, as required under the Guidelines for Clinical Trials in Human Subjects implemented pursuant to the Israeli Public Health Regulations (Clinical Trials in Human Subjects), as amended from time to time, and other applicable legislation. These regulations require authorization by the institutional ethics committee and general manager as well as from the Israeli Ministry of Health, except in certain circumstances, and in the case of genetic trials, special fertility trials and complex clinical trials, an additional authorization of the Israeli Ministry of Health's overseeing ethics committee. The institutional ethics committee must, among other things, evaluate the anticipated benefits that are likely to be derived from the project to determine if it justifies the risks and inconvenience to be inflicted on the human subjects, and the committee must ensure that adequate protection exists for the rights and safety of the participants as well as the accuracy of the information gathered in the course of the clinical testing. Since we intend to perform a portion of the clinical studies on certain of our therapeutic candidates in Israel, we will be required to obtain authorization from the ethics committee and general manager of each institution in which we intend to conduct our clinical trials, and in most cases, from the Israeli Ministry of Health.

Other Countries

In addition to regulations in the United States, the EU and Israel, we are subject to a variety of other regulations governing clinical trials and commercial sales and distribution of drugs in other countries. Whether or not our products receive approval from the FDA, approval of such products must be obtained by the comparable regulatory authorities of countries other than the United States before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials and product licensing vary greatly from country to country.

Related Matters

From time to time, legislation is drafted, introduced and passed in governmental bodies that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA or EMA and other applicable regulatory bodies to which we are subject. In addition, regulations and guidance are often revised or reinterpreted by the national agency in ways that may significantly affect our business and our therapeutic candidates. It is impossible to predict whether such legislative changes will be enacted, whether FDA or EMA regulations, guidance or interpretations will change, or what the impact of such changes, if any, may be. We may need to adapt our business and therapeutic candidates and products to changes that occur in the future.

Israeli Government Programs

Israel Innovation Authority

Research and Development Grants. A number of our therapeutic products have been financed, in part, through funding from the IIA in accordance with Research Law. Through December 31, 2021 we have received approximately $22.0 million in aggregate funding from the IIA and have paid the IIA approximately $7.0 million in royalties under our approved programs. As of December 31, 2021, we have no contingent obligation to the IIA other than for motixafortide. In connection with the in-licensing of motixafortide from Biokine, and as a condition to IIA consent to the transaction, we agreed to abide by any obligations resulting from funds previously received by Biokine from the IIA. The contingent liability to the IIA assumed by us relating to this transaction (which liability has no relation to the funding actually received by us) amounts to $3.5 million as of December 31, 2021. We have a full right of offset for amounts payable to the IIA from payments that we may owe to Biokine in the future.

Under the Research Law and the terms of the grants, royalties on the revenues derived from sales of products developed with the support of the IIA were payable to the Israeli government, generally at the rate of 3% although these terms would be different if we were to receive IIA approval to manufacture or to transfer the rights to manufacture our products developed with IIA grants outside of Israel. The obligation to make these payments terminates upon repayment of the amount of the received grants as adjusted for fluctuation in the dollar/shekel exchange rate, plus interest and any additional amounts as described below.

Pursuant to the Research Law and the tracks published by the IIA, recipients of funding from the IIA are prohibited from manufacturing products developed using IIA grants or derived from technology developed with IIA grants outside of Israel and from transferring rights to manufacture such products outside of Israel. However, the IIA could, in special cases, approve the transfer of manufacture or of manufacturing rights of a product developed in an approved program or which resulted therefrom, outside of Israel. If we were to receive approval to manufacture or to transfer the rights to manufacture our products developed with IIA grants outside of Israel, we would be required to pay an increased total amount of royalties (possibly up to 300% of the grant amounts plus interest), depending on the portion of total manufacturing that was performed outside of Israel. In addition, the royalty rate applicable to us could possibly increase. Such increased royalties constituted the total repayment amount required in connection with the transfer of manufacturing rights of IIA-funded products outside Israel. The tracks published by the IIA do enable companies to seek prior approval for conducting manufacturing activities outside of Israel without being subject to increased royalties (but resulting in a lower grant amount); however, the IIA rarely granted such prior approval.

Under the Research Law and the tracks published by the IIA, we are prohibited from transferring or licensing our IIA-financed technologies, technologies derived therefrom and related intellectual property rights and know-how outside of Israel except under limited circumstances and only with the approval of the IIA and generally upon making a payment to the IIA. The required approvals may not be received for any proposed transfer and, if received, we could be required to pay the IIA an amount calculated in accordance with the applicable formula set out in the tracks published by the IIA. The scope of the support received, the royalties that we already paid to the IIA, the amount of time that elapsed between the date on which the technology was transferred and the date on which the applicable project performance period for the IIA grants was completed, and the sale price and the form of transaction are to be taken into account in order to calculate the amount of the payment to the IIA. The repayment amount is subject to a maximum limit calculated in accordance with a formula set forth in guidelines published by the IIA. In addition, any decrease in the percentage of manufacture performed in Israel of any product or technology, as originally declared in the application to the IIA with respect to the product or technology, could require us to notify, or to obtain the approval of, the IIA, and could result in increased royalty payments to the IIA of up to 300% of the total grant amounts received in connection with the product or technology, plus interest, depending on the portion of total manufacturing that was performed outside of Israel.

Approval of the transfer or license of technology to residents of Israel is required and could be granted in specific circumstances, but only if the recipient agrees to abide by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties.

The State of Israel does not own intellectual property rights in technology developed with IIA funding and there is no restriction on the export of products manufactured using technology and know-how developed with IIA funding. The technology and know-how are, however, subject to transfer of technology and manufacturing rights restrictions as described above.

Israel Ministry of Health

Israel's Ministry of Health, which regulates medical testing, has adopted protocols that correspond, generally, to those of the FDA and the EMA, making it comparatively straightforward for studies conducted in Israel to satisfy FDA and the EMA requirements, thereby enabling medical technologies subjected to clinical trials in Israel to reach U.S. and EU commercial markets in an expedited fashion. Many members of Israel's medical community have earned international prestige in their chosen fields of expertise and routinely collaborate, teach and lecture at leading medical centers throughout the world. Israel also has free trade agreements with the United States and the EU.

C. Organizational Structure

Our corporate structure consists of BioLineRx Ltd., a substantially wholly owned U.K. subsidiary, Agalimmune Ltd., and one wholly owned inactive subsidiary, BioLineRx USA Inc.

D. Property, Plant and Equipment

We are headquartered in Modi'in, Israel. We entered into a lease agreement in August 2014, for an aggregate of 1,663 square meters (approximately 17,900 square feet) of space. Monthly rent is NIS 113,300 (approximately $35,400), including maintenance fees and parking. The initial term of the lease expired in June 2020, and we exercised our option to extend the lease through June 30, 2025. We have the option to extend the lease for two additional lease periods totaling up to an additional 5 years, each option at a 5% increase to the preceding lease payment amount.

This facility houses both our administrative and research operations and our central laboratory. The central laboratory consists of approximately 380 square meters (approximately 4,200 square feet) and includes a bioanalytical laboratory, a formulation laboratory and a tissue culture laboratory. Our bioanalytical laboratory has received GLP certification. All of our employees are based in this facility.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

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 — Risk Factors."

We are a late clinical-stage biopharmaceutical development company with a strategic focus on oncology. Our current development and commercialization pipeline consists of two clinical-stage therapeutic candidates – motixafortide (BL-8040), a novel peptide for the treatment of stem cell mobilization, solid tumors and AML, and AGI-134, an immuno-oncology agent in development for solid tumors. In addition, we have an off-strategy, legacy therapeutic product called BL-5010 for the treatment of skin lesions. We have generated our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a high probability of therapeutic and commercial success. To date, except for BL-5010, none of our therapeutic candidates have been approved for marketing or sold commercially. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case-by-case basis, the commercialization of our therapeutic candidates independently.

A. Operating Results

History of Losses

Since our inception in 2003, we have generated significant losses in connection with our research and development. As of December 31, 2021, we had an accumulated deficit of $305.0 million. We may continue to generate losses in connection with the research and development activities relating to our pipeline of therapeutic candidates. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we expect to continue to incur operating losses, which may be substantial over the next several years, and we expect to need to obtain additional funds to further pursue our research and development programs.

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), funding received from the IIA, payments received under out-licensing arrangements, and interest earned on investments. We expect to continue to fund our operations over the next several years through our existing cash resources, potential future milestone and royalty payments that we may receive from our existing out-licensing agreement, potential future upfront, milestone or royalty payments that we may receive from out-licensing transactions for our other therapeutic candidates, potential revenues that we may receive from the direct commercialization of our other therapeutic candidates, interest earned on our investments, and additional capital to be raised through public or private equity offerings or debt financings. As of December 31, 2021, we held $57.1 million of cash, cash equivalents and short-term bank deposits.

Revenues

Our revenues to date have been generated primarily from milestone payments under previously existing out-licensing agreements.

We expect our revenues, if any, for the next several years to be derived primarily from future payments under out- licensing agreement and other potential collaboration arrangements, including future royalties on product sales.

Research and Development

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, up-front and milestone payments under our license agreements, patent-related legal fees, costs of preclinical studies and clinical trials, drug and laboratory supplies and costs for facilities and equipment. We primarily use external service providers to manufacture our product candidates for clinical trials and for the majority of our preclinical and clinical development work. 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.

The following table identifies our current major research and development projects:

Project	Status	Expected Near Term Milestones
motixafortide	1. Phase 3 registration study in autologous stem cell mobilization (GENESIS) completed; top-line results announced May 2021 showed highly statistically significant evidence across all primary and secondary endpoints favoring motixafortide in combination with G-CSF ($p<0.0001$). In addition, the combination was found to be safe and well tolerated. Pharmaco-economic studies showed positive results regarding the cost-effectiveness of using motixafortide versus both G-CSF alone and plerixafor in combination with G-CSF. Pre-NDA meeting with FDA in December 2021 resulted in FDA agreeing that our GENESIS study is sufficient to support an NDA submission.	1. NDA submission in mid-2022
	2. Phase 2a study in pancreatic cancer (COMBAT/KEYNOTE-202) completed; full results showing improvement in all endpoints announced December 2020	2. Evaluation and planning of next clinical development steps, including discussions towards potential collaborations and development of a protocol for a randomized controlled study
	3. Phase 2 investigator-initiated study in first-line PDAC patients	3. Data from the study is anticipated in mid-2022*
	4. Phase 1b study in patients with ARDS secondary to COVID-19 and other respiratory viral infections	4. Results of the preliminary analysis are expected in 2022*
AGI-134	Phase 1/2a study, ongoing	Initial proof-of-mechanism of action and efficacy results expected in second half of 2022

*These studies are investigator-initiated studies; therefore, the timelines are ultimately controlled by the independent investigators and are subject to change.

We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes, we are unable to estimate with any certainty the costs we will incur in the continued development of the therapeutic candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each product candidate. If we are not able to enter into an out-licensing arrangement with respect to any therapeutic candidate prior to the commencement of later stage clinical trials, we may fund the trials for the therapeutic candidate ourselves.

While we are currently focused on advancing each of our product development projects, our future research and development expenses will depend on the clinical success of each therapeutic candidate, as well as ongoing assessments of each therapeutic candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future out-licensing arrangements, when such out-licensing 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 — Risk Factors — If we or our licensees are unable to obtain U.S. and/or foreign regulatory approval for our therapeutic candidates, we will be unable to commercialize our therapeutic candidates."

As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain therapeutic candidates or projects in order to focus our resources on more promising therapeutic candidates or projects. Completion of clinical trials by us or our licensees may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a therapeutic candidate.

The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the number of patients that participate in the clinical trials;

- the duration of patient follow-up;
- whether the patients require hospitalization or can be treated on an out-patient basis;
- the development stage of the therapeutic candidate; and
- the efficacy and safety profile of the therapeutic candidate.

We expect our research and development expenses to remain our most significant cost as we continue the advancement of our clinical trials and preclinical product development projects and place significant emphasis on in-licensing new product candidates. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires expenditure of substantial resources. Any failure or delay in completing 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. Due to the factors set forth above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation for employees in business development and marketing functions. Other significant sales and marketing costs include costs for marketing and communication materials, professional fees for outside market research and consulting, legal services related to partnering transactions and travel costs.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including accounting, finance, legal, investor relations, information technology and human resources. Other significant general and administration costs include facilities costs, professional fees for outside accounting and legal services, travel costs, insurance premiums and depreciation.

Non-Operating Expense and Income

Non-operating expense and income includes fair-value adjustments of liabilities on account of the warrants issued in equity financings we carried out in July 2017, February 2019, May 2020 and June 2020. These fair-value adjustments are highly influenced by our share price at each period end (revaluation date). Non-operating expense and income also includes issuance expenses of the ATM sales agreements between us and H.C. Wainwright & Co., LLC, or HCW, entered into in September 2020 and September 2021, and the pro-rata share of issuance expenses from the placements related to the warrants. Sales-based royalties and other revenue from the license agreement with Perrigo have also been included as part of non-operating income, as the out-licensed product is not an integral part of our strategy and the amounts are not material.

Financial Expense and Income

Financial expense and income consist of interest earned on our cash, cash equivalents and short-term bank deposits; interest expense related to our loan from Kreos Capital; bank fees and other transactional costs. In addition, it may also include gains/losses on foreign exchange hedging transactions, which we carry out from time to time to protect against a portion of our NIS-denominated expenses (primarily compensation) in relation to the dollar.

Significant Accounting Policies and Estimates

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2021. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepare in accordance with IFRS. The preparation of these financial statements requires us to make estimates using assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates, including those described in greater detail below. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which impact the carrying value of our assets and liabilities that are not readily apparent from other sources. Actual results will differ from these estimates and such differences may be significant.

Revenue Recognition

We recognize revenues in accordance with International Financial Reporting Standards No. 15, or IFRS 15. IFRS 15, "Revenue from Contracts with Customers," which was issued in May 2014, amends revenue recognition requirements and establishes principles for reporting information about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The standard replaces International Auditing Standard, or IAS, 18, "Revenue" and IAS 11, "Construction Contracts" and related interpretations. The standard is effective for annual periods beginning on or after January 1, 2018, and we have adopted it as of that date.

IFRS 15 introduces a five-step model for recognizing revenue from contracts with customers, as follows:

- identify the contract with a customer;
- identify the performance obligations in the contract;
- determine the transaction price;
- allocate the transaction price to the performance obligations in the contract; and
- recognize revenue when (or as) the entity satisfies a performance obligation.

Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. This process involves estimating the level of service performed on our behalf and the associated cost incurred in instances where we have not been invoiced or otherwise notified of actual costs. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for preclinical development, clinical trials and manufacturing of clinical materials. We account for expenses associated with these external services by determining the total cost of a given study based on the terms of the related contract. We accrue for costs incurred as the services are being provided by monitoring the status of the trials and the invoices received from our external service providers. In the case of clinical trials, the estimated cost normally relates to the projected costs of treating the patients in our trials, which we recognize over the estimated term of the trial according to the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. As actual costs become known to us, we adjust our accruals.

Investments in Financial Assets

The primary objective of our investment activities is to preserve principal while maximizing the income that 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. Due to the short-term maturities of our investments to date, their carrying value has always approximated their fair value.

A financial asset is classified in this category if our management has designated it as a financial asset upon initial recognition, because it is managed, and its performance is evaluated, on a fair-value basis in accordance with a documented risk management or investment strategy. Our investment policy with regard to excess cash, as adopted by our Board of Directors, is composed of the following objectives: (i) preserving investment principal; (ii) providing liquidity; and (iii) providing optimum yields pursuant to the policy guidelines and market conditions. The policy provides detailed guidelines as to the securities and other financial instruments in which we are allowed to invest. In addition, in order to maintain liquidity, investments are structured to provide flexibility to liquidate at least 50% of all investments within 15 business days. Information about these assets, including details of the portfolio and income earned, is provided internally on a quarterly basis to our key management personnel and on a semi-annual basis to the Investment Monitoring Committee of our Board of Directors. Any divergence from this investment policy requires approval from our Board of Directors.

Stock-based Compensation

We account for stock-based compensation arrangements in accordance with the provisions of IFRS 2. IFRS 2 requires companies to recognize stock compensation expense for awards of equity instruments based on the grant-date fair value of those awards (with limited exceptions). The cost is recognized as compensation expense over the life of the instruments, based upon the grant-date fair value of the equity or liability instruments issued. The fair value of our stock-based compensation grants is computed as of the grant date based on the Black-Scholes model, using the standard parameters established in that model including estimates relating to volatility of our stock, risk-free interest rates, estimated life of the equity instruments issued and the market price of our stock. As our ordinary shares are publicly traded on the TASE, we do not need to estimate their fair market value. Rather, we use the actual closing market price of our ordinary shares on the date of grant, as reported by the TASE.

Warrants

In connection with the direct placement to BVF Partners L.P., or BVF Partners, of 566,372 ADSs in July 2017, we issued (i) Series A warrants to purchase 198,230 ADSs at an exercise price of $30.00 per ADS and (ii) Series B warrants to purchase 198,230 ADSs at an exercise price of $60.00 per ADS. All the warrants are exercisable for a period of four years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrants are not qualified for classification as an equity instrument and have therefore been classified as a non-current financial liability. The warrants expired in July 2021.

In connection with a loan transaction entered into with Kreos Capital, we issued a warrant to purchase 63,837 ADSs at an exercise price of $14.10 per ADS. The warrant is exercisable for a period of ten years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrant is not qualified for classification as an equity instrument and has therefore been classified as a non-current financial liability.

In connection with a public offering we completed in February 2019, we issued warrants to purchase 1,866,667 ADSs at an exercise price of $11.25 per ADS. The warrants are exercisable for a period of five years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrant is not qualified for classification as an equity instrument and has therefore been classified as a non-current financial liability.

In connection with a registered direct offering we completed in May 2020, we issued warrants to purchase 5,142,859 ADSs at an exercise price of $2.25 per ADS and also issued warrants to purchase 257,143 ADSs at an exercise price of $2.1875 per ADS. The warrants are exercisable for a period of two and one-half years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrant is not qualified for classification as an equity instrument and has therefore been classified as a non-current financial liability.

In connection with a registered direct offering we completed in June 2020, we issued warrants to purchase 2,510,286 ADSs at an exercise price of $2.25 per ADS and also issued warrants to purchase 125,514 ADSs at an exercise price of $2.1875 per ADS. The warrants are exercisable for a period of five years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrant is not qualified for classification as an equity instrument and has therefore been classified as a non-current financial liability.

In connection with an underwritten public offering we completed in January 2021, we issued warrants to purchase 718,750 ADSs at an exercise price of $3.00 per ADS. The warrants are exercisable for a period of five years from the date of issuance. The warrants have been classified as shareholder’s equity.

Results of Operations -- Overview

Revenues

We did not record any revenues for the years ended December 31, 2019, 2020 and 2021.

Cost of revenues

We did not record any cost of revenues for the years ended December 31, 2019, 2020 and 2021.

Comparison of the Year Ended December 31, 2021 to the Year Ended December 31, 2020

Research and development expenses

Research and development expenses for the year ended December 31, 2021 were $19.5 million, an increase of $1.3 million, or 7.1%, compared to $18.2 million for the year ended December 31, 2020. The increase resulted primarily from an increase in expenses associated with the AGI-134 study, as well as an increase in payroll and related-expenses due to a company-wide salary reduction related to the COVID-19 pandemic in the comparable 2020 period, offset by lower expenses associated with the completed motixafortide GENESIS and COMBAT clinical trials.

Sales and marketing expenses

Sales and marketing expenses for the year ended December 31, 2021 were $1.0 million, an increase of $0.2 million, or 19.4% compared to $0.8 million for the year ended December 31, 2020. The increase resulted primarily from an increase in consultancy services related to motixafortide.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2021 were $4.3 million, an increase of $0.4, or 10.0% compared to $3.9 million for the year ended December 31, 2020. The increase resulted primarily from an increase in directors' and officers' insurance expenses.

Non-operating income (expense), net

We recognized net non-operating expenses of $1.8 million for the year ended December 31, 2021 compared to net non-operating expenses of $5.7 million for the year ended December 31, 2020. Non-operating expenses for both periods primarily relate to fair-value adjustments of warrant liabilities on our balance sheet and issuance expenses of the ATM.

Financial income (expense), net

We recognized net financial expenses of $0.4 million for the year ended December 31, 2021 compared to net financial expenses of $1.4 million for the year ended December 31, 2020. Net financial expenses for both periods primarily relate to interest paid on loans, offset by investment income earned on our bank deposits.

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

Research and development expenses

Research and development expenses for the year ended December 31, 2020 were $18.2 million, a decrease of $5.2 million, or 22.5%, compared to $23.4 million for the year ended December 31, 2019. The decrease resulted primarily from termination of the BATTLE clinical study for motixafortide in 2019, from lower expenses associated with the motixafortide COMBAT clinical trial and from lower expenses associated with the AGI-134 study, as well as a decrease in share-based compensation and payroll due to a company-wide salary reduction related to the COVID-19 pandemic.

Sales and marketing expenses

Sales and marketing expenses for the year ended December 31, 2020 were $0.8 million, similar to the year ended December 31, 2019.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2020 were $3.9 million, an increase of $0.1, or 2.6% compared to $3.8 million for the year ended December 31, 2019. The increase resulted primarily from an increase in directors' and officers' insurance expenses and share-based compensation, offset by small decreases in a number of G&A expenses.

Non-operating income (expense), net

We recognized net non-operating expenses of $5.7 million for the year ended December 31, 2020 compared to net non-operating income of $4.2 million for the year ended December 31, 2019. Non-operating expenses for the year ended December 31, 2020 primarily relate to fair-value adjustments of warrant liabilities on our balance sheet, warrant offering expenses and ATM issuance expenses. Non-operating income for the year ended December 31, 2019 primarily relates to fair-value adjustments of warrant liabilities on our balance sheet, offset by warrant offering expenses.

Financial income (expense), net

We recognized net financial expenses of $1.4 million for the year ended December 31, 2020 compared to net financial expenses of $1.5 million for the year ended December 31, 2019. Net financial expenses for both periods primarily relate to interest paid on loans, offset by investment income earned on our bank deposits.

Quarterly Results of Operations

The following tables show our unaudited quarterly statements of operations for the periods indicated. We have prepared this quarterly information on a basis consistent with our audited consolidated financial statements and we believe it includes all adjustments, consisting of normal recurring adjustments necessary for a fair statement of the information shown. Operating results for any quarter are not necessarily indicative of results for a full fiscal year.

	Three Months Ended							
	March 31	**June 30**	**Sept. 30**	**Dec. 31**	**March 31**	**June 30**	**Sept. 30**	**Dec. 31**
	2020				**2021**			
	(in thousands of U.S. dollars)							
Consolidated Statements of Operations								
Revenues	–	–	–	–	–	–	–	–
Cost of revenues	–	–	–	–	–	–	–	–
Research and development expenses	(5,422)	(4,640)	(3,484)	(4,627)	(4,278)	(5,139)	(4,923)	(5,126)
Sales and marketing expenses	(175)	(182)	(309)	(174)	(154)	(330)	(247)	(272)
General and administrative expenses	(1,243)	(744)	(856)	(1,071)	(1,017)	(1,044)	(1,047)	(1,200)
Operating loss	(6,840)	(5,566)	(4,649)	(5,872)	(5,449)	(6,513)	(6,217)	(6,598)
Non-operating income (expenses), net	469	(843)	294	(5,621)	(4,561)	(217)	710	2,238
Financial income	140	35	39	22	117	130	52	260
Financial expenses	(414)	(396)	(302)	(517)	(299)	(242)	(261)	(204)
Net loss	(6,645)	(6,770)	(4,618)	(11,988)	(10,192)	(6,842)	(5,716)	(4,304)

Our quarterly revenues and operating results of operations have varied in the past and can be expected to vary in the future due to numerous factors. We believe that period-to-period comparisons of our operating results are not necessarily meaningful and should not be relied upon as indications of future performance.

B. Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through public and private offerings of our equity securities, payments received under our strategic licensing and collaboration arrangements, interest earned on investments and funding from the IIA. At December 31, 2021, we had $57.1 million in cash, cash equivalents and short-term bank deposits. We have invested substantially all of our available cash funds in short-term bank deposits.

On October 31, 2017, we entered into that certain At-the-Market Sales Agreement, or the BTIG Sales Agreement, dated October 31, 2017, by and between us and BTIG, LLC, or BTIG. Pursuant to the BTIG Sales Agreement, we could elect from time to time, to offer and sell through BTIG, acting as sales agent, our ADSs having an aggregate offering price of up to $30 million through an "at the market offering" as defined in Rule 415(a)(4), or the BTIG ATM Offering. From the effective date of the BTIG Sales Agreement through September 24, 2020, we sold an aggregate of 2,923,553 ADSs for an aggregate offering price of $13.0 million. On May 26, 2020, we terminated the prospectus supplement dated April 17, 2020 related to the BTIG ATM Offering, and we terminated the BTIG Sales Agreement effective September 24, 2020.

On May 28, 2020, we sold to certain institutional investors an aggregate of 5,142,859 ADSs in a registered direct offering at $1.75 per ADS, resulting in gross proceeds of 9.0 million. In addition, we issued to the investors unregistered warrants to purchase up to an aggregate of 5,142,859 ADSs in a private placement. The warrants are immediately exercisable and will expire two and one-half years from issuance at an exercise price of $2.25 per ADS, subject to adjustment as set forth therein. The warrants may be exercised on a cashless basis if on or following three months after issuance there is no effective registration statement registering the ADSs underlying the warrants. We paid an aggregate of $0.6 million in placement agent fees plus certain expenses and issued unregistered placement agent warrants to purchase up to an aggregate of 257,143 ADSs on substantially the same terms as the warrants except they have an exercise price of $2.1875 per ADS.

On June 3, 2020, we sold to certain institutional investors an aggregate of 2,510,286 ADSs in a registered direct offering at $1.75 per ADS, resulting in gross proceeds of $4.4 million. In addition, we issued to the investors unregistered warrants to purchase up to an aggregate of 2,510,286 ADSs in a private placement. The warrants are immediately exercisable and will expire two and one-half years from issuance at an exercise price of $2.25 per ADS, subject to adjustment as set forth therein. The warrants may be exercised on a cashless basis if on or following three months after issuance there is no effective registration statement registering the ADSs underlying the warrants. We paid an aggregate of $0.3 million in placement agent fees plus certain expenses and issued unregistered placement agent warrants to purchase up to an aggregate of 125,514 ADS on substantially the same terms as the warrants except they have an exercise price of $2.1875 per ADS.

On September 25, 2020, we entered into the Original HCW Offering Agreement with HCW. Pursuant to the Original HCW Offering Agreement, we were able to offer and sell, from time to time, at our option, up to $25.0 million of our ADSs through an "at-the-market" equity offering program under which HCW agreed to act as sales agent. From the effective date of the Original HCW Offering Agreement through September 3, 2021, we sold an aggregate of 7,381,101 ADSs for an aggregate offering price of $24.5 million. On September 3, 2021, the Original HCW Offering Agreement was terminated.

On January 22, 2021, we sold 14,375,000 ADSs at a price to the public of $2.40 per ADS, resulting in gross proceeds of $34.5 million. HCW acted as the sole book-running manager for the offering. We paid an aggregate of $2.4 million in placement agent fees and expenses and issued placement agent warrants to purchase 718,750 ADS. The placement agent warrants are immediately exercisable at a price of $3.00 per ADS, subject to adjustment in certain circumstances, and expire five years from the commencement of sales under the offering.

On September 3, 2021, we entered into the New HCW Offering Agreement with HCW, pursuant to which we may offer and sell, at our option, up to $25.0 million of our ADSs through an "at-the-market" equity program under which HCW agreed to act as sales agent. As of March 15, 2022, we have sold 402,327 of our ADSs for total gross proceeds of approximately $1.1 under the New HCW Offering Agreement.

Net cash used in operating activities for the year ended December 31, 2021 was $23.6 million, compared to $23.2 million for the year ended December 31, 2020 and $22.7 million for the year ended December 31, 2019. The $0.4 million increase in 2021 was primarily the result of an increase in research and development expenses. The $0.5 million increase in 2020 was primarily the result of a decrease in accounts payable and accruals.

Net cash used in investing activities for the year ended December 31, 2021 was $38.2 million, compared to net cash provided by financing activities of $16.7 million for the year ended December 31, 2020 and $5.3 million for the year ended December 31, 2019. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits during the respective periods.

Net cash provided by financing activities for the year ended December 31, 2021 was $57.7 million, compared to $17.9 million for the year ended December 31, 2020 and $19.2 million for the year ended December 31, 2019. The cash flows in 2021 primarily reflect the underwritten public offering of our ADSs in January 2021, warrant exercises, and net proceeds from the ATM facility, offset by repayments of the loan from Kreos Capital. The cash flows in 2020 primarily reflect the registered direct offerings of our ADSs in May and June 2020, as well as net proceeds from the ATM facility, offset by repayments of the loan from Kreos Capital. The cash flows in 2019 primarily reflect the underwritten public offering of our ADSs in February 2019, as well as net proceeds from the ATM program.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash and other resources will be sufficient to fund our current projected cash requirements into the first half of 2024, we will require additional financing in the future to fund our operations. Additional financing may not be available on acceptable terms, if at all. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues we receive under our collaboration or licensing arrangements;
- the costs of the development and expansion of our operational and commercial infrastructure;
- the costs and timing of obtaining regulatory approval of our therapeutic candidates;
- the ability of our collaborators to achieve development milestones, marketing approval and other events or developments under our collaboration agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of establishing sales and marketing capabilities or contracting with third parties to provide these capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;
- the magnitude of our general and administrative expenses;
- any cost that we may incur under current and future licensing arrangements relating to our therapeutic candidates;
- market conditions;
- payments to the IIA; and
- the impact of the COVID-19 pandemic and the Russian invasion of Ukraine, which may exacerbate the magnitude of the factors discussed above.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through payments received under our collaborations, debt or equity financings, or by out-licensing other product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, or at all.

If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts.

Contractual Obligations

The following table summarizes our significant contractual obligations at December 31, 2021:

	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
	(in thousands of U.S. dollars)				
Car leasing obligations	213	97	116	-	-
Premises leasing obligations	1,954	444	844	666	-
Purchase commitments	8,432	6,636	1,596	200	-
Total	10,599	7,177	2,556	866	-

The premises leasing obligations in the foregoing table include our commitments under the lease agreement for our facility in Modi'in. See "Item 4. Information on the Company — Property, Plant and Equipment." The initial term of the lease began on June 15, 2015 and expired June 2020. We have exercised an option to extend the lease through June 30, 2025 and have the option to extend the lease for two additional lease periods totaling up to an additional 5 years, each option at a 5% increase to the preceding lease payment amount. The monthly lease fee is $26,000. In addition, we pay building maintenance charges of $9,400 per month.

The foregoing table does not include our in-licensing agreements. Under our in-licensing agreements, we are obligated to make certain payments to our licensors upon the achievement of agreed-upon milestones. We are unable at this time to estimate the actual amount or timing of the costs we will incur in the future under these agreements; however, we do not expect any material financial milestone obligations to be achieved within the next 12 months. Some of the in-licensing agreements are accompanied by consulting, support and cooperation agreements, pursuant to which we are required to pay the licensors a fixed monthly amount, over a period stipulated in the applicable agreement, for their assistance in the continued research and development under the applicable license. All of our in-licensing agreements are terminable at-will by us upon prior written notice of 30 to 90 days. We are unable at this time to estimate the actual amount or timing of the costs we will incur in the future under these agreements. See "Item 4. Information on the Company — Business Overview — In-Licensing Agreements."

C. Research and Development, Patents and Licenses

For our research and development policies, see "Item 4 — Information on the Company — Business Overview — Our Strategy." For information regarding patents, see Item 4 — Information on the Company — Intellectual Property." For information regarding licenses, see "Item 4 — Information on the Company — Collaboration and Out-Licensing Arrangements" and Item 4 — Information on the Company — In-Licensing Agreements."

D. Trend Information

We are a development stage company and it is not possible for us to predict with any degree of accuracy the outcome of our research, development or commercialization efforts. As such, it is not possible for us to predict with any degree of accuracy any known trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our net sales or revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause reported financial information to not necessarily be indicative of future operating results or financial conditions. However, to the extent possible, certain trends, uncertainties, demands, commitments and events are in this "Operating and Financial Review and Prospects."

E. Critical Accounting Estimates

We prepare our financial statements in accordance with International Financial Reporting Standards, or IFRS. In doing so, we must make estimates and assumptions that affect our reported amounts of assets, liabilities and expenses, as well as related disclosure of contingent assets and liabilities. In some cases, we could reasonably have used different accounting policies and estimates. Changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ materially from our estimates. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations will be affected. Significant estimates include, but are not limited to, those related to deferred revenue, revenue recognition, stock-based compensation and fair value of marketable debt securities. For further significant accounting policies please see Note 2 to our audited consolidated financial statements of this annual report. We believe that our accounting policies contained therein are critical in fully understanding and evaluating our financial condition and operating results.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Executive Officers and Directors

The following table sets forth information for our executive officers and directors as of March 15, 2022. Unless otherwise stated, the address for our directors and officers is c/o BioLineRx Ltd., 2 HaMa'ayan Street, Modi'in 7177871, Israel.

Name	Age	Position(s)
Philip A. Serlin, CPA, MBA	61	Chief Executive Officer
Mali Zeevi, CPA	46	Chief Financial Officer
Ella Sorani, Ph.D.	54	Chief Development Officer
Abi Vainstein-Haras, M.D.	47	Chief Medical Officer
Aharon Schwartz, Ph.D. (1)	79	Chairman of the Board
Michael J. Anghel, Ph.D. (1)(4)	83	Director
Nurit Benjamini, MBA (1)(2)(3)(4)	55	External Director
B.J. Bormann, Ph.D. (1)	63	Director
Raphael Hofstein, Ph.D. (1)(2)(3)	72	Director
Avraham Molcho, M.D. (1)(2)(3)	64	External Director
Sandra Panem, Ph.D. (1)	75	Director

(1) Independent director under applicable Nasdaq Capital Market and SEC rules, as affirmatively determined by our Board.

(2) A member of our audit committee.

(3) A member of our compensation committee.

(4) A member of our investment monitoring committee.

Philip A. Serlin, CPA, MBA, has served as our Chief Executive Officer since October 2016. From May 2009 to October 2016, Mr. Serlin served as our Chief Financial and Operating Officer. From January 2008 to August 2008, Mr. Serlin served as the Chief Financial Officer and Chief Operating Officer of Kayote Networks Inc. From January 2006 to December 2007, he served as the Chief Financial Officer of Tescom Software Systems Testing Ltd., an IT services company publicly traded in both Tel Aviv and London. His background also includes senior positions at Chiaro Networks Ltd. and at Deloitte, where he was head of the SEC and U.S. Accounting Department at the National Office in Tel Aviv, as well as seven years at the SEC at its Washington, D.C., headquarters. Mr. Serlin is a CPA and holds a B.Sc. in accounting from Yeshiva University and a Master's degree in economics and public policy from The George Washington University.

Mali Zeevi, CPA, has served as our Chief Financial Officer since October 2016. Prior to becoming Chief Financial Officer, Ms. Zeevi served as our Senior Director of Finance and Reporting beginning in 2011 and as our Director of Finance and Reporting beginning in 2009. Before joining BioLineRx, Ms. Zeevi was employed by Tescom Software Systems Testing Ltd., her last position there being Vice President Finance. Ms. Zeevi also served as a CPA at Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited. She holds a B.A. in business and accountancy from the College of Management Academic Studies in Israel.

Ella Sorani, Ph.D., has served as our Chief Development Officer since January 2021. From February 2017 to December 2020, Dr. Sorani served as our Vice President Research and Development. Before joining BioLineRx, from 2000 through 2016, Dr. Sorani served in a number of management positions in the global R&D division at Teva Pharmaceutical Industries Ltd. In her most recent position as Senior Director and Global Project Leader, Dr. Sorani led the development of one of Teva's leading innovative late stage compounds. Dr. Sorani holds a B.Sc. in chemistry and an M.Sc. and Ph.D. in pharmacology, all from Tel Aviv University.

Abi Vainstein-Haras, M.D., has served as our Chief Medical Officer since January 2021. From January 2017 to December 2020, Dr. Vainstein-Haras served as our Vice President Clinical Development. From June 2014 to January 2017, Dr. Vainstein-Haras served as our Senior Medical Director responsible for the clinical development of all our clinical phase projects. Prior to joining the Company, from 2012 to 2014, she served as the Director and Clinical Program Leader for COPAXONE® at Teva, and from 2007 to 2012, she served in several medical positions in Innovative R&D at Teva. Dr. Vainstein-Haras holds an M.D. from the University of Buenos Aires and is licensed to practice medicine in Israel.

Aharon Schwartz, Ph.D., has served as the Chairman of our Board of Directors since 2004. He served in a number of positions in Teva from 1975 through 2011, the most recent being Vice President, Head of Teva Innovative Ventures from 2008. Dr. Schwartz is currently a member of the board of directors of Protalix Ltd. (NYSE American:PLX) and Barcode Ltd. He also works as an independent consultant. Dr. Schwartz received his Ph.D. in organic chemistry from the Weizmann Institute, his M.Sc. in organic chemistry from the Technion and a B.Sc. in chemistry and physics from the Hebrew University of Jerusalem. In addition, Dr. Schwartz holds a Ph.D. from the Hebrew University of Jerusalem in the history and philosophy of science.

Michael J. Anghel, Ph.D., has served on our Board of Directors since 2010 and on our Investment Monitoring Committee since 2010. From 1977 to 1999, he led the Discount Investment Corporation Ltd. (of the IDB Group) activities in the fields of technology and communications. Dr. Anghel was instrumental in founding Tevel, one of the first Israeli cable television operators and later in founding Cellcom Israel Ltd. (NYSE:CEL), the second Israeli cellular operator. In 1999, he founded CAP Ventures, an advanced technology investment company. From 2004 to 2005, Dr. Anghel served as CEO of DCM, the investment banking arm of the Israel Discount Bank (TASE:DSCT). Over the years, Dr. Anghel has been involved in founding and managing various technology enterprises and has served on the Boards of Directors of various major Israeli corporations and financial institutions, many of them publicly traded in the U.S. and Israel. During the past two years, he completed long term tenures as director on the boards of: Partner Communications Company, Ltd. (Nasdaq:PTNR, TASE:PTNR), Strauss Group Ltd. (TASE:STRS), and Orbotech Ltd. (Nasdaq:ORBK), He currently serves as director on the boards of InMode Ltd. (Nasdaq:INMD) and Ellomay Capital Ltd. (NYSE American: ELLO). Prior to launching his business career, Dr. Anghel served as a full-time member of the faculty of the Recanati Graduate School of Business Administration of the Tel Aviv University, where he taught finance and corporate strategy. He currently serves as Chairman of the Tel Aviv University's Executive Program. Dr. Anghel holds a B.A. (Economics) from the Hebrew University in Jerusalem and an MBA and Ph.D. (Finance) from Columbia University, New York.

Nurit Benjamini, MBA, has served as an external director on our Board of Directors and as the chairperson of our Audit Committee of our Board of Directors since 2010. In addition, Ms. Benjamini has served on our Investment Monitoring Committee since 2010 and on our Compensation Committee since 2012. Since December 2013, Ms. Benjamini has served as the Chief Financial Officer of Crazy Labs Ltd. (formerly TabTale Ltd.), a company that creates fresh mobile content for everyone. From 2011 to 2013, Ms. Benjamini served as the Chief Financial Officer of Wix.com Ltd. (Nasdaq:WIX); from 2007 through 2011, she served as the Chief Financial Officer of CopperGate Communications Ltd. (now Sigma Designs Israel Ltd., a subsidiary of Sigma Designs Inc. (Nasdaq:SIGM)); and from 2000 through 2007, she served as the Chief Financial Officer of Compugen Ltd. (Nasdaq: CGEN). Ms. Benjamini serves on the board of directors, and as chairperson of the audit committee, of Caesarstone Ltd. (Nasdaq: CSTE). Ms. Benjamini holds a B.A. in economics and business and an M.B.A. in finance, both from Bar Ilan University, Israel.

BJ Bormann, Ph.D., has served on our Board of Directors since August 2013. Dr. Bormann currently serves as the Vice President of Translational Science and Network Alliances at The Jackson Laboratory, a non-profit organization focused on the genetic basis of disease. Dr. Bormann was previously the Chief Executive Officer of Supportive Therapeutics, LLC, a Boston based company that is developing two molecules for use in the supportive care of oncology patients. In the past several years Dr. Bormann has held executive positions in several biotechnology companies including NanoMedical Systems (Austin, Texas), Harbour Antibodies (Rotterdam, The Netherlands) and Pivot Pharmaceuticals (PVTF: OTC listed). Prior to these engagements, Dr. Bormann was Senior Vice President responsible for world-wide alliances, licensing and business development at Boehringer Ingelheim Pharmaceuticals, Inc. from 2007 to 2013. From 1996 to 2007, she served in a number of positions at Pfizer, Inc., the last one being Vice President of Pfizer Global Research and Development and world-wide Head of Strategic Alliances. Dr. Bormann serves on the board of directors of various companies, including Xeris BioPharma, Inc (Nasdaq:XERS) and NanoMedical Systems (private). Dr. Bormann received her Ph.D. in biomedical science from the University of Connecticut Health Center and her B.Sc. from Fairfield University in biology. Dr. Bormann completed postdoctoral training at Yale Medical School in the department of pathology.

Raphael Hofstein, Ph.D., has served on our Board of Directors since 2003, our Audit Committee since 2007 and our Compensation Committee since 2012. Dr. Hofstein has served as the President and Chief Executive Officer of MaRS Innovation (a commercialization company for 15 of Toronto's universities, institutions and research institutes plus the MaRS Discovery District) from June 2009 to March 2020. From 2000 through June 2009, Dr. Hofstein was the President and Chief Executive Officer of Hadasit Medical Research Services and Development Ltd., or Hadasit, the technology transfer company of Hadassah University Hospitals. He has served as chairman of the board of directors of Hadasit since 2006. Prior to joining Hadasit, Dr. Hofstein was the President of Mindsense Biosystems Ltd. and the Business Unit Director of Ecogen Inc. and has held a variety of other positions, including manager of R&D and chief of immunochemistry at the International Genetic Science Partnership. Dr. Hofstein serves on the board of directors of numerous companies. Dr. Hofstein received his Ph.D. and M.Sc. from the Weizmann Institute of Science, and his B.Sc. in chemistry and physics from the Hebrew University in Jerusalem. Dr. Hofstein completed postdoctoral training at Harvard Medical School in both the departments of biological chemistry and neurobiology.

Avraham Molcho, M.D., has served as an external director on our Board of Directors and on our Audit Committee since 2010. In addition, Dr. Molcho has served on our Compensation Committee since 2012. Dr. Molcho is the co-founder of Biolojic Design Ltd., a technology platform that encourages human antibody discovery. In 2012, he became the co-founder of Ayana Pharma Ltd. (formerly DoxoCure), a privately-held company engaged in the manufacturing of liposome-based therapeutics. He served as Ayana's Chief Executive Officer and director until 2019. From 2006 through 2008, Dr. Molcho served as the Chief Executive Officer and Chairman of Neovasc Medical, a privately-held Israeli medical device company. From 2006 until 2019, Dr. Molcho was a venture partner at Forbion Capital Partners, a Dutch life sciences venture capital firm. From 2001 through 2006, Dr. Molcho was a managing director and the head of life sciences of Giza Venture Capital and, in that capacity, was involved in the founding of our company. He was also the Deputy Director General of Abarbanel Mental Health Center, the largest acute psychiatric hospital in Israel, from 1999 to 2001. Dr. Molcho holds an M.D. from Tel-Aviv University School of Medicine and an MBA from Tel-Aviv University Recanati Business School.

Sandra Panem, Ph.D., has served on our Board of Directors since February 2014. She is currently a managing partner at Cross Atlantic Partners, which she joined in 2000. She is also co-founder and President of NeuroNetworks Fund, a not-for-profit venture capital fund focusing on epilepsy, schizophrenia and autism. From 1994 to 1999, Dr. Panem was President of Vector Fund Management, the then asset management affiliate of Vector Securities International. Prior thereto, Dr. Panem served as Vice President and Portfolio Manager for the Oppenheimer Global BioTech Fund, a mutual fund that invested in public and private biotechnology companies. Previously, she was Vice President at Salomon Brothers Venture Capital, a fund focused on early and later-stage life sciences and technology investments. Dr. Panem was also a Science and Public Policy Fellow in economic studies at the Brookings Institution, and an Assistant Professor of Pathology at the University of Chicago. Dr. Panem currently serves on the board of directors of Acorda Therapeutics, Inc. (Nasdaq:ACOR). Previously, Dr. Panem served on numerous boards of public and private companies, including Martek Biosciences (Nasdaq:MATK), IBAH Pharmaceuticals (Nasdaq:IBAH), Confluent Surgical, Molecular Informatics and Labcyte, Inc. She received a B.S. in biochemistry and a Ph.D. in microbiology from the University of Chicago.

B. Compensation

Employment Agreements

We have entered into written employment agreements with each of our executive officers, the terms of which are consistent with the provisions of our Compensation Policy for Executives and Directors, or Compensation Policy, which was approved by our shareholders in July 2019, and amended by our shareholders in March 2020 and April 2021. 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 law.

In addition, we have entered into agreements with each executive officer and director pursuant to which we have agreed to indemnify each of them to the fullest extent permitted by law to the extent that these liabilities are not covered by directors' and officers' insurance. The terms of these agreements and of our directors' and officers' insurance are consistent with the provisions of the Compensation Policy.

Compensation of Directors and Senior Management

The following table presents in the aggregate all compensation we paid to all of our directors and senior management as a group for the year ended December 31, 2021. The table does not include any amounts we paid to reimburse any of such persons for costs incurred in providing us with services during this period.

	Salaries, fees, commissions and bonuses	**Pension, retirement, options and other similar benefits**
	(in thousands of U.S. dollars)	
All directors and senior management as a group, consisting of 11 persons	1,735	867

In accordance with the Companies Law, the following table presents information regarding compensation actually received by our four executive officers during the year ended December 31, 2021.

Name and Position	Salary	Social Benefits[1]	Bonuses	Value of Options Granted[2]	All Other Compensation[3]	Total
	(in thousands of U.S. dollars)					
Philip A. Serlin Chief Executive Officer	290	81	251	259	23	904
Mali Zeevi Chief Financial Officer	186	52	135	67	18	458
Abi Vainstein-Haras Chief Medical Officer	204	47	119	69	21	460
Ella Sorani Chief Development Officer	212	60	122	66	20	480

(1) "Social Benefits" include payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds, vacation pay and recuperation pay as mandated by Israeli law.

(2) Consists of amounts recognized as share-based compensation expense on the Company's statement of comprehensive loss for the year ended December 31, 2021.

(3) "All Other Compensation" includes automobile-related expenses pursuant to the Company's automobile leasing program, telephone, basic health insurance and holiday presents.

For additional information concerning our equity compensation plan, see "— Beneficial Ownership of Executive Officers and Directors — Equity Compensation Plan."

C. Board Practices

Board of Directors

According to the Companies Law, the management of our business is vested in our Board of Directors. However, certain of our committees are required to have a majority of independent directors. Our Board of Directors may exercise all powers and may take all actions that are not specifically granted to our shareholders. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our Board of Directors. Executive officers are appointed by and serve at the discretion of our Board of Directors, subject to any applicable employment agreements we have entered into with the executive officers.

Under the Companies Law, we are not required to have a majority of independent directors. We are required to appoint at least two external directors, unless we qualify as an Eligible Company (*as defined below*) and opt to follow an exemption provided under the Relief Regulations (*as defined below*). See "— External Directors."

According to our Articles of Association, our Board of Directors must consist of at least five and not more than 10 directors, including external directors. Currently, our Board of Directors consists of seven directors, including two external directors as required by the Companies Law. Pursuant to our Articles of Association, other than the external directors, for whom special election requirements apply under the Companies Law as detailed below, our directors are elected at a general or extraordinary meeting of our shareholders and serve on the Board of Directors until they are removed by the majority of our shareholders at a general or extraordinary meeting of our shareholders or upon the occurrence of certain events, in accordance with the Companies Law and our Articles of Association. In addition, our Articles of Association allow our Board of Directors to appoint directors, other than external directors, to fill vacancies on the Board of Directors to serve until the next general meeting or extraordinary meeting, or earlier if required by our Articles of Association or applicable law. We have held elections for each of our non-external directors at each annual meeting of our shareholders since our initial public offering in Israel. External directors are elected for an initial term of three years and may be elected, under certain conditions, to two additional terms, although the term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including Nasdaq, may be further extended under certain conditions. External directors may be removed from office only pursuant to the terms of the Companies Law. Our last annual meeting of shareholders was held in December 2021. For additional information concerning external directors, see "— External Directors."

The Companies Law provides that an Israeli company may, under certain circumstances, exculpate an office holder from liability with respect to a breach of his duty of care toward the company if appropriate provisions allowing such exculpation are included in its articles of association. See "— Exculpation, insurance and indemnification of office holders." Our Articles of Association contain such provisions, and we have entered into agreements with each of our office holders undertaking to indemnify them to the fullest extent permitted by law, to the extent that these liabilities are not covered by insurance.

In accordance with the exemption available to foreign private issuers under applicable Nasdaq rules, we do not follow the requirements of the Nasdaq Rules with regard to the process of nominating directors, and instead follow Israeli law and practice, in accordance with which our Board of Directors is authorized to recommend to our shareholders director nominees for election, and, in some circumstances, our shareholders may nominate candidates for election as directors by the shareholders' general meeting.

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

The term office holder is defined in the Companies Law as a general manager, chief business manager, deputy general manager, vice general manager, executive vice president, vice president, or any other person assuming the responsibilities of any of the foregoing positions, without regard to such person's title, or a director or any other manager directly subordinate to the general manager. Each person listed above under "Executive Officers and Directors" is an office holder under the Companies Law.

Chairman of the Board. Under the Companies Law, a person cannot hold the role of both chairman of the board of directors and chief executive officer of a company, without shareholder approval by special majority and for periods of time not exceeding three years each. Furthermore, a person who is directly or indirectly subordinate to a chief executive officer of a company may not serve as the chairman of the board of directors of that company and the chairman of the board of directors may not otherwise serve in any other capacity in a company or in a subsidiary of that company other than as a director or the chairman of the board of directors of such a subsidiary.

External Directors

Under Israeli law, the boards of directors of companies whose shares are publicly traded are required to include at least two members who qualify as external directors. Each of our current external directors, Dr. Avraham Molcho and Ms. Nurit Benjamini, was re-elected as an external director by our shareholders in July 2019 for an additional three-year term.

External directors must be elected by majority vote of the shares present and voting at a shareholders meeting, provided that either:

- the majority of the shares that are voted at the meeting, including at least a majority of the shares held by non-controlling shareholders or shareholders who do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) who voted at the meeting, excluding abstentions, vote in favor of the election of the external director; or

- the total number of shares held by non-controlling, disinterested shareholders (as described in the preceding bullet point) that are voted against the election of the external director does not exceed 2% of the aggregate voting rights in the company.

After an initial term of three years, external directors may be re-elected to serve in that capacity for up to two additional terms of three years provided that either (a) the board of directors has recommended such re-election and such re-election is approved by a majority vote at a shareholders' meeting, subject to the conditions described above for election of external directors, (b) (1) the re-election has been recommended by one or more shareholders holding at least 1% of the company's voting rights and is approved by a majority of non-controlling, disinterested shareholders who hold among them at least 2% of the company's voting rights; and (2) the external director who has been nominated in such fashion by the shareholders is not a linked or competing shareholder, and does not have or has not had, on or within the two years preceding the date of such person's appointment to serve as another term as external director, any affiliation with a linked or competing shareholder, or (c) the external director has proposed himself for reappointment and the reappointment was approved by the majority described in (b)(1) above. The term "linked or competing shareholder" means the shareholder(s) who nominated the external director for reappointment or a material shareholder of the company holding more than 5% of the shares in the company, provided that at the time of the reappointment, such shareholder(s) of the company, the controlling shareholder of such shareholder(s) of the company, or a company under such shareholder(s) of the company's control, has a business relationship with the company or are competitors of the company; the Israeli Minister of Justice, in consultation with the Israeli Securities Authority, or ISA, may determine that certain matters will not constitute a business relationship or competition with the company. The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including Nasdaq, may be extended beyond the initial three terms permitted under the Companies Law indefinitely in increments of additional three-year terms, provided in each case that the following conditions are met: (a) the audit committee and the board of directors confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the re-election for such additional period(s) is beneficial to the company; (b) the re-election is approved by the shareholders by a special majority required for the re-election of external directors; and (c) the term of office of the external director, and the considerations of the audit committee and the board of directors in deciding to recommend re-election of the external director for such additional term of office, are presented to the shareholders prior to the vote on re-election. External directors may be removed from office by the same percentage of shareholders required for their election or by a court, in each case, only under limited circumstances, including ceasing to meet the statutory qualification for appointment or violating the duty of loyalty to the company. If an external directorship becomes vacant and there are less than two external directors on the board of directors at the time, then the board of directors is required under the Companies Law to call a shareholders' meeting immediately to appoint a replacement external director. Each committee of the board of directors that exercises the powers of the board of directors must include at least one external director (unless the company is an Eligible Company and opted to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees). Under the Companies Law external directors of a company are prohibited from receiving, directly or indirectly, any compensation from the company other than for their services as external directors pursuant to the provisions and limitations set forth in regulations promulgated under the Companies Law.

A person may not serve as an external director if (a) the person is a relative of a controlling shareholder of a company or (b) at the date of the person's appointment or within the prior two years, the person, the person's relatives, entities under the person's control, the person's partner, the person's employer, or anyone to whom that person is subordinate, whether directly or indirectly, have or have had any affiliation with (1) a company, (2) a company's controlling shareholder at the time of such person's appointment or (3) any entity that is either controlled by the company or under common control with the company at the time of such appointment or during the prior two years. If a company does not have a controlling shareholder or a shareholder who holds company shares entitling him to vote at least 25% of the votes in a shareholders meeting, then a person may not serve as an external director if, such person or such person's relative, partner, employer or any entity under the person's control, has or had, on or within the two years preceding the date of the person's appointment to serve as external director, any affiliation with the chairman of the company's board, chief executive officer, a substantial shareholder who holds at least 5% of the issued and outstanding shares of the company or voting rights which entitle him to vote at least 5% of the votes in a shareholders meeting, or the chief financial officer of the company.

The term "affiliation" includes:

- an employment relationship;
- a business or professional relationship even if not maintained on a regular basis (excluding insignificant relationships);
- control; and
- service as an office holder, excluding service as a director in a private company prior to the first offering of its shares to the public if such director was appointed as a director of the private company in order to serve as an external director following the public offering.

The term "relative" is defined as a spouse, sibling, parent, grandparent or descendant; a spouse's sibling, parent or descendant; and the spouse of each of such persons.

In addition, no person may serve as an external director if that person's professional activities create, or may create, a conflict of interest with that person's responsibilities as a director or otherwise interfere with that person's ability to serve as an external director or if the person is an employee of the ISA or of an Israeli stock exchange. Furthermore, a person may not continue to serve as an external director if he or she received direct or indirect compensation from us for his or her role as a director. This prohibition does not apply to compensation paid or given for service as an external director in accordance with regulations promulgated under the Companies Law or amounts paid pursuant to indemnification and/or exculpation contracts or commitments and insurance coverage.

Following the termination of an external director's service on a board of directors, such former external director and his or her spouse and children may not be provided a direct or indirect benefit by the company, its controlling shareholder or any entity under its controlling shareholder's control. This includes engagement to serve as an executive officer or director of the company or a company controlled by its controlling shareholder or employment by, or providing services to, any such company for consideration, either directly or indirectly, including through a corporation controlled by the former external director, for a period of two years (and for a period of one year with respect to relatives of the former external director).

If at the time an external director is appointed all members of the board of directors are of the same gender, the external director must be of the other gender. A director of one company may not be appointed as an external director of another company if a director of the other company is acting as an external director of the first company at such time.

The Companies Law provides that an external director must meet certain professional qualifications or have financial and accounting expertise and that at least one external director must have financial and accounting expertise. However, if at least one of our other directors (1) meets the independence requirements of the Exchange Act, (2) meets the standards of the Nasdaq Rules for membership on the audit committee and (3) has financial and accounting expertise as defined in the Companies Law and applicable regulations, then neither of our external directors is required to possess financial and accounting expertise as long as both possess other requisite professional qualifications. Our Board of Directors is required to determine whether a director possesses financial and accounting expertise by examining whether, due to the director's education, experience and qualifications, the director is highly proficient and knowledgeable with regard to business-accounting issues and financial statements, to the extent that the director is able to engage in a discussion concerning the presentation of financial information in the company's financial statements, among others. Furthermore, our Board of Directors is also required to take into consideration a director's education, experience and knowledge in any of the following: (1) accounting issues and accounting control issues characteristic to the segment in which the company operates and to companies of the size and complexity of the company, (2) the functions of the external auditor and the obligations imposed on such auditor, and (3) preparation of financial reports and their approval in accordance with the Companies Law and the Israeli Securities Law, 5728-1968, or the Israeli Securities Law. The regulations define a director with the requisite professional qualifications as a director who satisfies one of the following requirements: (1) the director holds an academic degree in either economics, business administration, accounting, law or public administration; (2) the director either holds an academic degree in any other field or has completed another form of higher education in the company's primary field of business or in an area which is relevant to the office of an external director; or (3) the director has at least five years of experience serving in any one of the following, or at least five years of cumulative experience serving in two or more of the following capacities: (1) a senior business management position in a corporation with a substantial scope of business; (2) a senior position in the company's primary field of business; or (3) a senior position in public administration. Our Board of Directors has determined that Ms. Nurit Benjamini possesses "accounting and financial" expertise, and that both of our external directors possess the requisite professional qualifications.

In addition, the Companies Regulations (Relief for Companies the Shares of which are Registered for Trading Outside of Israel) – 2000, or the Relief Regulations, provide an exemption for companies the shares of which are listed for trading on specified exchanges outside of Israel, including Nasdaq, provided that: (i) such company does not have a controlling shareholder; and (ii) the company complies with the requirements of the foreign securities laws and stock exchange regulations applicable to companies which are incorporated under the laws of such foreign countries with regard to appointing independent directors and composition of the audit and compensation committees, or collectively, Eligible Companies. Any Eligible Company which opts to comply with the applicable foreign securities laws and stock exchange regulations shall be exempt from the following rules under the Companies Law: (i) the requirement to have at least two external directors appointed to serve in a public company; (ii) that at least one of the external directors is required to have financial and accounting expertise and the rest are required to have professional expertise; and (iii) that all of the board committees which are empowered and authorized to exercise any of the board's authorities must consist of at least one external director. The exemption from these rules under the Relief Regulations requires that the board be composed of both male and female directors.

Audit Committee

Under the Companies Law, the board of directors of a public company must appoint an audit committee. The audit committee must be comprised of at least three directors, including all of the external directors, and one of the external directors must serve as chairperson of the committee. Additionally, a majority of the members of the committee must be independent directors. The audit committee of a company may not include:

- the chairman of the company's board of directors;
- a controlling shareholder or a relative of a controlling shareholder of the company (as each such term is defined in the Companies Law); or
- any director employed by the company, by a controlling shareholder of the company or by any other entity controlled by a controlling shareholder of the company, or any director who provides services to the company, to a controlling shareholder of the company or to any other entity controlled by a controlling shareholder of the company on a regular basis (other than as a member of the board of directors), or any other director whose main source of income derives from a controlling shareholder of the company.

The term "controlling shareholder" is defined in the Companies Law as a shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint the majority of the directors of the company or its general manager.

A majority of the total number of then-serving members of an audit committee shall constitute a quorum for the transaction of business at the audit committee meetings, provided, that the majority of the members present at such meeting are unaffiliated directors and at least one of such members is an external director.

The audit committee of a publicly traded company must consist of a majority of independent directors. An "independent director" is defined as either an external director or as a director who meets the following criteria:

- he or she meets the qualifications for being appointed as an external director, except for (i) the requirement that the director be an Israeli resident (which does not apply to companies such as ours whose securities have been offered outside of Israel or are listed outside of Israel) and (ii) the requirement for accounting and financial expertise or professional qualifications; and

- he or she has not served as a director of the company for a period exceeding nine consecutive years. For this purpose, a break of less than two years in the service shall not be deemed to interrupt the continuation of the service.

Any person who is not eligible to serve on the audit committee is further restricted from participating in its meetings and votes, unless the chairman of the audit committee determines that such person's presence is necessary in order to present a certain matter, provided however, that company employees who are not controlling shareholders or relatives of such shareholders may be present in the meetings but not for the actual votes, and likewise, company counsel or company secretary who are not controlling shareholders or relatives of such shareholders may be present in the meetings and for the decisions if such presence is requested by the audit committee.

Pursuant to Nasdaq Rules, our Board of Directors may appoint one director to our Audit Committee who (1) is not an Independent Director as defined in Nasdaq Marketplace Rule 5605(a)(2), (2) meets the criteria set forth in Section 10A(m)(3) under the Exchange Act, and (3) is not one of our current officers or employees or "family member," as defined in Nasdaq Marketplace Rule 5605(a)(2), of an officer or employee, if our Board of Directors, under exceptional and limited circumstances, determines that the appointment is in our best interests and the best interest of our shareholders, and our Board of Directors discloses, in our next annual report subsequent to the determination, the nature of the relationship and the reasons for that determination.

The members of our Audit Committee are Ms. Nurit Benjamini (Chairperson), Dr. Avraham Molcho and Dr. Raphael Hofstein.

Our Board of Directors has determined that Ms. Nurit Benjamini (Chairperson) qualifies as an audit committee financial expert as defined by rules of the SEC.

In November 2012, our Board of Directors adopted an audit committee charter that added to the responsibilities of our Audit Committee under the Companies Law, setting forth the responsibilities of the audit committee consistent with the rules of the SEC and the Nasdaq Rules, including the following:

- oversight of the company's independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to our Board of Directors in accordance with Israeli law;

- recommending the engagement or termination of the office of our internal auditor; and

- reviewing and pre-approving the terms of audit and non-audit services provided by our independent auditors.

Our Audit Committee provides assistance to our Board of Directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our Audit Committee also oversees the audit efforts of our independent accountants and takes those actions it deems necessary to satisfy itself that the accountants are independent of management. Pursuant to the Companies Law, the audit committee of a company shall be responsible for: (i) determining whether there are delinquencies in the business management practices of a company, including in consultation with an internal auditor or independent auditor, and making recommendations to the company's board of directors to improve such practices; (ii) determining whether to approve certain related party transactions (including compensation of office holders or transactions in which an office holder has a personal interest and whether such transaction is material or otherwise an extraordinary transaction); (iii) where the company's board of directors approves the working plan of the internal auditor, examining such working plan before its submission to the board and proposing amendments thereto; (iv) examining internal control and the internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of his responsibilities (taking into consideration the special needs and size of a company); (v) examining the scope of the auditor's work and compensation and submitting its recommendation with respect thereto to the corporate body considering the appointment thereof (either the board or the general meeting of shareholders); and (vi) establishing procedures for the handling of employees' complaints as to the management of the business and the protection to be provided to such employees. The responsibilities of the audit committee under the Companies Law also include the following matters: (i) the establishment of procedures to be followed in respect of related party transactions with a controlling shareholder (where such are not extraordinary transactions), which may include, where applicable, the establishment of a competitive process for such transaction, under the supervision of the audit committee, or individual, or other committee or body selected by the audit committee, in accordance with criteria determined by the audit committee; and (ii) to determine procedures for approving certain related party transactions with a controlling shareholder, which having been determined by the audit committee not to be extraordinary transactions, were also determined by the audit committee not to be negligible transactions. Under the Companies Law, the approval of the audit committee is required for specified actions and transactions with office holders and controlling shareholders. See "— Approval of Related Party Transactions under Israeli Law."

Pursuant to the Relief Regulations, companies the shares of which are listed for trading on specified exchanges outside of Israel, including Nasdaq, and which qualify as Eligible Companies, are exempt from the following rules regarding the audit committee under the Companies Law: (i) the committee shall be comprised of at least three members, who shall include all of the external directors, and the majority of the members shall be independent; (ii) certain persons may not be members of the audit committee; (iii) the controlling shareholder or his relatives shall not be members of the audit committee; (iv) the chairman of the audit committee shall be an external director; (v) a person who is prohibited from being a member of the audit committee shall not be present at the committee's meetings; (vi) if the committee also serves as a financial reports committee, the rules applicable to the financial reports committee shall apply; and (vii) the legal quorum shall be the majority of the committee members, provided that the majority of directors present are independent, at least one of whom is an external director.

Compensation Committee

Pursuant to the Companies Law, the board of directors of an Israeli publicly-traded company is required to appoint a compensation committee comprised of at least three members, including all of the external directors of a company, and one of the external directors must serve as chairman of the committee. A majority of the members of the Compensation Committee are required to be external directors and the rest of the members shall be members whose terms of service are as required under the Companies Law. Such compensation committee may not include:

- the chairman of the company's board of directors;
- a controlling shareholder or a relative of a controlling shareholder of the company (as each such term is defined in the Companies Law); or
- any director employed by the company, by a controlling shareholder of the company or by any other entity controlled by a controlling shareholder of the company, or any director who provides services to the company on a permanent basis, to a controlling shareholder of the company or to any other entity controlled by a controlling shareholder of the company on a regular basis (other than as a member of the board of directors), or any other director whose main source of income derives from a controlling shareholder of the company.

A majority of the total number of then-serving members of a compensation committee shall constitute a quorum for the transaction of business at the compensation committee meetings. The compensation committee of a publicly-traded company must consist of a majority of external directors.

Pursuant to the Relief Regulations, companies the shares of which are listed for trading on specified exchanges outside of Israel, including Nasdaq and qualify as Eligible Companies are exempt from the following rules regarding the compensation committee under the Companies Law: (i) the board of a public company is required to appoint a compensation committee; and (ii) the compensation committee shall be comprised of at least three members, all of the external directors shall be members and shall constitute the majority of its members and the rest of the members shall be members whose terms of service are as required under the Companies Law.

Any person who is not eligible to serve on the compensation committee is further restricted from participating in its meetings and votes, unless the chairman of the compensation committee determines that such person's presence is necessary in order to present a certain matter, provided however, that company employees who are not controlling shareholders or relatives of such shareholders may be present in the meetings but not for the actual votes, and likewise, company counsel and secretary who are not controlling shareholders or relatives of such shareholders may be present in the meetings and for the decisions if such presence is requested by the compensation committee.

The responsibilities of the compensation committee include the following:

- to make recommendations to the board of directors as to a compensation policy for officers, as well as to recommend once every three years to extend the compensation policy, subject to receipt of the required corporate approvals;
- to make recommendations to the board of directors as to any updates to the compensation policy which may be required;
- to review the implementation of the compensation policy by the company;
- to approve transactions relating to terms of office and employment of certain company office holders, that require the approval of the compensation committee pursuant to the Companies Law; and
- to exempt, under certain circumstances, a transaction relating to terms of office and employment from the requirement of approval of the shareholders meeting.

In November 2012, in order to comply with certain requirements of the Companies Law which had been enacted shortly prior to that, our Board of Directors established a Compensation Committee, comprised of Ms. Nurit Benjamini and Dr. Avraham Molcho, our two external directors, and Dr. Raphael Hofstein. Ms. Nurit Benjamini serves as the Chairperson of our Compensation Committee.

Under the Companies Law, a board of directors of an Israeli publicly-traded company, following the recommendation of the compensation committee, is required to establish a compensation policy, to be approved by the shareholders of the company, and pursuant to which the terms of office and compensation of the company's officer holders will be decided.

A company's compensation policy shall be determined based on, and take into account, certain parameters set forth in Section 267B(a) and Parts A and B of Annex 1A of the Companies Law, which were legislated as part of Amendment 20.

Under the Companies Law, the board of directors of a publicly traded company is obligated, after considering the recommendations of the compensation committee, to adopt a compensation policy according to which the compensation of the company's office holders will be determined. The final adoption of the compensation policy is subject to the approval of the shareholders of the company, and such approval is subject to certain special majority requirements, as set forth in the Companies Law, pursuant to which one of the following must be met:

(i) the majority of the votes includes at least a majority of all the votes of shareholders who are not controlling shareholders of the company or who do not have a personal interest in the compensation policy and participating in the vote; abstentions shall not be included in the total of the votes of the aforesaid shareholders; or

(ii) the total of opposing votes from among the shareholders described in subsection (i) above does not exceed 2% of all the voting rights in the company.

For this purpose, under the Companies Law "personal interest" is defined as: (1) a shareholder's personal interest in the approval of an act or a transaction of the company, including (i) the personal interest of his or her relative (which includes for these purposes any members of his/her (or his/her spouse's) immediate family or the spouses of any such members of his or her (or his/her spouse's) immediate family); and (ii) a personal interest of a body corporate in which a shareholder or any of his/her aforementioned relatives serves as a director or the chief executive officer, owns at least 5% of its issued share capital or its voting rights or has the right to appoint a director or chief executive officer, but (2) excluding a personal interest arising solely from the fact of holding shares in the company or in a body corporate.

Nonetheless, even if the shareholders of the company do not approve the compensation policy, the board of directors of a company may approve the compensation policy, provided that the compensation committee and, thereafter, the board of directors resolved, based on detailed, documented, reasons and after a second review of the compensation policy, that the approval of the compensation policy is for the benefit of the company.

In December 2013, a general meeting of our shareholders approved our first Executive Compensation Policy which had been recommended by our Compensation Committee and approved by our Board of Directors. At the annual general meeting of our shareholders in July 2019, our shareholders approved our current Compensation Policy which was amended at a general meeting of our shareholders in March 2020 and April 2021. Below is a summary discussion of the main provisions of the Compensation Policy:

The Compensation Policy includes, among other issues prescribed by the Companies Law, a framework for establishing the terms of office and employment of our office holders, a recoupment policy and guidelines with respect to the structure of the variable pay of our office holders.

Compensation is considered performance-based to the extent that a direct link is maintained between compensation and performance and that rewards are consistent with long-term stakeholder value creation. At the company level, we analyze the overall compensation trends of the market in order to make informed decisions about our compensation approach.

According to the Compensation Policy, the fixed components of our office holder compensation will be examined at least every two years and compared to the market. Our Board of Directors may change the amount of the fixed components for one or more of our office holders after receiving a recommendation for such from our Compensation Committee, provided such change is within the limits determined by the Compensation Policy. The change may be made if our Board of Directors concludes that such a change would promote our goals, operating plans and objectives and after taking into account the business and legal implications of the proposed change and its impact on our internal labor relations. Any such changes are subject to formal approval by the relevant parties. Our Board of Directors will has the authority to approve a change in the incentive structure of all executive officers, including but not limited to the chief executive officer, up to an immaterial amount in any one year (immaterial being defined as a change of up to 5% of an officer's total compensation). The fixed component of compensation remunerates the specific role covered and scope of responsibilities. It also reflects the experience and skills required for each position, as well as the level of excellence demonstrated and the overall quality of the office holder's contribution to our business. The weighting of fixed compensation within the overall package is designed to reduce the risk of excessively risk-oriented behavior, to discourage initiatives focused on short-term results which might jeopardize our mid and long-term business sustainability and value creation, and to allow us a flexible compensation approach. We offer our employees benefit plans based on common practice in the local labor market of the office holder.

As for the variable components of compensation, the types and amounts of such components will be determined with an aim at creating maximum matching between the Compensation Policy and our operating plan and objectives. Variable components of compensation will be primarily based on measurable long-term criteria. Nevertheless, we are allowed to base a non-material part of variable compensation on qualitative non-measurable criteria which focus on the office holder's contribution to the Company. Our variable compensation aims to remunerate for achievements by directly linking pay to performance outcomes in the short and long term. To strengthen the alignment of shareholder interests and the interests of management and employees, performance measurements reflect our actual results overall, as well as of the individual office holder. To support the aforementioned principles, we provide two types of variable compensation: short-term - annual bonus; and long-term - stock option plans.

Annual bonuses will be based on achievement of the business goals set out in our annual operating plan approved by the board of directors at the beginning of each year. The operating plan encompasses all aspects of our activities and as such sets the business targets for each member of the management team. Consequently, our Compensation Committee and Board of Directors should be able to judge the suitability of a bonus payment by deliberating retrospectively at year end and comparing actual performance and target achievements against the forecasted operating plan. The annual bonus mechanism will be directly tied to meeting objectives - both our business objectives and the office holder's personal objectives. The Board of Directors' satisfaction with the officer's performance will also affect the bonus amount. Annual bonus payments are subject to the limitations set out in the Compensation Policy and also subject to the discretion of our Compensation Committee and approval by the Board of Directors. In order to maintain some measure of flexibility, after calculating the compensation amount, the Board of Directors may exercise discretion about the final amount of the bonus.

Equity-based compensation may be granted in any form permitted under our share incentive plan in effect from time to time and shall be made in accordance with the terms of such share incentive plan. Equity-based compensation to office holders shall be granted from time to time and be individually determined and awarded according to the performance, educational background, prior business experience, qualifications, role and the personal responsibilities of each officer. The vesting period will generally be four years, with the vesting schedule to be determined in accordance with market compensation trends. Our policy is to grant equity-based compensation with exercise prices at market value. Furthermore, in order to create a ceiling for the variable compensation: (1) the aggregate value of annual grants to any one office holder (based on the Black Scholes calculation on the date of grant) will be no more than the higher of 2% of our market capitalization at the end of the measurement period or $1.5 million; and (2) it is our intention that the maximum outstanding equity awards under its share incentive plan will not exceed 12% of our total fully-diluted share capital. Our Board of Directors may, following approval by our Compensation Committee, make provisions with respect to the acceleration of the vesting period of any office holder's awards, including, without limitation, in connection with a corporate transaction involving a change of control.

We have also established a defined ratio between the variable and the fixed components of compensation, as well as a maximum amount for all variable components as of the date on which they are paid (or as of the grant date for non-cash variable equity components), and subject to the limitations on variable compensation components which are set out in the Compensation Policy.

In addition, we have established guidelines under which an office holder will refund to us part of the compensation received, if it was paid based on information that was retroactively restated in our financial reports. Office holders shall be required to make restitution for any payments made based on our operating performance, if such payments were based on false or restated financial statements prepared at any time during the three years preceding discovery of the error.

All compensation arrangements of office holders are to be approved in the manner prescribed by applicable law. Our Compensation Committee will review the Compensation Policy on an annual basis, and monitor its implementation, and recommend to our Board of Directors and shareholders to amend the Compensation Policy as it deems necessary from time to time. The term of the Compensation Policy is three years from the date of its adoption, or July 2, 2022. Following such three-year term, the Compensation Policy, including any revisions recommended by our Compensation Committee and approved by our Board of Directors, as applicable, will be brought once again to the shareholders for approval.

Nominating Committee

Our Board of Directors does not currently have a nominating committee, having availed BioLineRx of the exemption available to foreign private issuers under the Nasdaq Rules. See "Item 16G. Corporate Governance."

Investment Monitoring Committee

Our Board of Directors has established an Investment Monitoring Committee which consists of the following four members: Directors Dr. Michael Anghel (Chairperson) and Ms. Nurit Benjamini; Ms. Mali Zeevi, our Chief Financial Officer; and Mr. Raziel Fried, our Treasurer and Budgetary Control Director. The function of the Investment Monitoring Committee includes providing recommendations to our Board of Directors regarding investment guidelines and performing an on-going review of the fulfillment of established investment guidelines. The Investment Monitoring Committee convenes for a meeting in accordance with our needs, but in any event at least twice per year.

Internal Auditor

Under the Companies Law, the board of directors of an Israeli public company must appoint an internal auditor recommended by the audit committee and nominated by the board of directors. An internal auditor may not be:

- a person (or a relative of a person) who holds more than 5% of the company's shares;
- a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;
- an executive officer or director of the company; or
- a member of the company's independent accounting firm.

The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. Our internal auditor is Tali Yaron Adv. (LLB, LLM), a director at Deloitte Israel.

Approval of Related Party Transactions under Israeli Law

Fiduciary duties of office holders

The Companies Law imposes a duty of care and a duty of loyalty on all office holders of a company. The duty of care of an office holder is based on the duty of care set forth in connection with the tort 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 a duty to use reasonable means, in light of the circumstances, to obtain:

- information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to these actions.
- The duty of loyalty requires an office holder to act in good faith and for the benefit of the company, and includes 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 performed in breach of the duty of loyalty of an office holder 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, as described below.

Disclosure of personal interests of an office holder and approval of acts and transactions

The Companies Law requires that an office holder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obliged to disclose such information if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered as an extraordinary transaction.

The term personal interest is defined under the Companies Law to include the personal interest of a person in an action or in the business of a company, including the personal interest of such person's relative or the interest of any corporation in which the person or any of his/her relatives serves as a director or the chief executive officer, owns at least 5% of its issued share capital or its voting rights or has the right to appoint a director or chief executive officer, but excluding a personal interest stemming solely from the fact of holding shares in such corporation. A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the interest of the office holder with respect to his or her vote on behalf of the shareholder for whom he or she holds a proxy even if such shareholder itself has no personal interest in the approval of the matter. An office holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction.

Under the Companies Law, an extraordinary transaction which requires approval is defined 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.

Under the Companies Law, once an office holder has complied with the disclosure requirement described above, 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, or approve an action by the office holder that would otherwise be deemed a breach of duty of loyalty. However, a company may not approve a transaction or action that is adverse to the company's interest or that is not performed by the office holder in good faith.

Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder, a transaction with a third party in which the office holder has a personal interest, and an action of an office holder that would otherwise be deemed a breach of duty of loyalty requires approval by the board of directors. Our Articles of Association do not provide otherwise. If the transaction or action considered is (i) an extraordinary transaction or (ii) an action of an office holder that would otherwise be deemed a breach of duty of loyalty and may have a material impact on a company's profitability, assets or liabilities, then audit committee approval is required prior to approval by the board of directors.

Under the Companies Law, a transaction with an office holder in a public company regarding his or her terms of office and employment should be determined in accordance with the company's compensation policy. Nonetheless, provisions were established that allow a company, under special circumstances, to approve terms of office and employment that are not in line with the approved compensation policy. The following are required for the approval of the terms of office or employment of the officers of a public company:

- A transaction with an office holder in a public company that is neither a director nor the chief executive officer regarding his or her terms of office and employment requires approval by the (i) compensation committee; and (ii) the board of directors. Approval of terms of office and employment for such officers which do not comply with the compensation policy may nonetheless be approved subject to two cumulative conditions: (i) the compensation committee and thereafter the board of directors, approved the terms after having taken into account the various considerations and mandatory requirements set forth in the Companies Law with respect to office holder compensation, and (ii) the shareholders of the company have approved the terms by means of the following special majority requirements, or the Special Majority Requirements, as set forth in the Companies Law, pursuant to which the shareholder approval must either include at least one-half of the shares held by non-controlling and disinterested shareholders who actively participate in the voting process (without taking abstaining votes into account), or, alternatively, the total shareholdings of the non-controlling and disinterested shareholders who vote against the transaction must not represent more than 2% of the voting rights in the company. However, the transaction may still be approved despite shareholder rejection, provided that a company's compensation committee and thereafter the board of directors have determined to approve the proposal, based on detailed reasoning, after having re-examined the terms of office and employment, and taken the shareholder rejection into consideration.

- A transaction with the chief executive officer in a public company regarding his or her terms of office and employment requires approval by the (i) compensation committee; (ii) the board of directors; and (iii) the shareholders of the company by the Special Majority Requirements. Approval of terms of office and employment for the chief executive officer which do not comply with the compensation policy may nonetheless be approved subject to two cumulative conditions: (i) the compensation committee and thereafter the board of directors, approved the terms after having taken into account the various considerations and mandatory requirements set forth in the Companies Law with respect to office holder compensation and (ii) the shareholders of the company have approved the terms by means of the Special Majority Requirements, as detailed above. However, a transaction with a chief executive officer that is not approved by shareholders may still be approved despite shareholder rejection, provided that a company's compensation committee and thereafter the board of directors have determined to approve the proposal, based on detailed reasoning, after having re-examined the terms of office and employment, and taken the shareholder rejection into consideration. In addition, the compensation committee may exempt the transaction regarding terms of office and employment with a candidate for the office of chief executive officer where such officer has no relationship with the controlling shareholder or the company from shareholder approval if it has found, based on detailed reasons, that bringing the transaction to the approval of the shareholders meeting shall prevent the employment of such candidate by the company. Such approval may be given only in respect of terms of office and employment which are in accordance with the company's compensation policy.

- A transaction with a director who is not the chief executive officer of a public company regarding his or her terms of office and engagement requires approval by the (i) compensation committee; (ii) the board of directors; and (iii) the shareholders of the company. Approval of terms of office and employment for directors of a company which do not comply with the compensation policy may nonetheless be approved subject to two cumulative conditions: (i) the compensation committee and thereafter the board of directors, approved the terms after having taken into account the various considerations and mandatory requirements set forth in the Companies Law with respect to office holder compensation and (ii) the shareholders of the company have approved the terms by means of the Special Majority Requirements, as detailed above. In addition, pursuant to a relief provided under the Companies Regulations (Relief in Interested Party Transactions), 2000, the compensation committee may exempt the transaction regarding terms of office and engagement with a non-executive director, if the compensation committee and board of directors determined that such terms of office are only for the benefit of the company, or if the compensation terms of the director do not exceed the maximum compensation paid to external directors pursuant to the applicable regulations.

A director who has a personal interest in a matter that is considered at a meeting of the board of directors or the audit committee may generally not be present at the meeting or vote on the matter unless a majority of the directors or members of the audit committee have a personal interest in the matter, or, unless the chairman of the audit committee or board of directors (as applicable) determines that he or she should be present to present the transaction that is subject to approval. If a majority of the directors have a personal interest in the matter, such matter also requires approval of the shareholders of the company by the Special Majority Requirements.

Disclosure of personal interests of a controlling shareholder and approval of transactions

Under the Companies Law, the disclosure requirements that apply to an office holder also apply to a controlling shareholder of a public company. See "— Audit Committee" for the general definition of "controlling shareholder" under the Companies Law. In connection with matters governing: (i) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, (ii) certain private placements in which the controlling shareholder has a personal interest, (iii) certain transactions with a controlling shareholder or relative with respect to services provided to or employment by the company, (iv) the terms of employment and compensation of the general manager, and (v) the terms of employment and compensation of office holders of the company when such terms deviate from the compensation policy previously approved by the company's shareholders, the definition of "controlling shareholder" also includes shareholders that hold 25% or more of the voting rights if no other shareholder owns more than 50% of the voting rights in the company (and the holdings of two or more shareholders which each have a personal interest in such matter will be aggregated for the purposes of determining such threshold).

Under the Companies Law, 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, as well as transactions for the provision of services whether directly or indirectly by a controlling shareholder or his or her relative, or a company such controlling shareholder controls, require the approval of the audit committee, the board of directors and the shareholders, in that order. Transactions concerning the terms of engagement of a controlling shareholder or a controlling shareholder's relative, whether as an office holder or an employee, require the approval of the compensation committee, the board of directors and the shareholders, in that order. In addition, the approval of such extraordinary transactions by the shareholders require at least a majority of the shares voted by the shareholders of the company participating and voting in a shareholders' meeting, provided that one of the following requirements is fulfilled:

- at least 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.

If such transaction concerns the terms of office and employment of such controlling shareholder, in his capacity as an office holder or an employee of the company, such terms of office and employment approved by the compensation committee and board of directors shall be in accordance with the compensation policy of the company. Nonetheless, the compensation committee and the board of directors may approve terms of office and compensation of a controlling shareholder which do not comply with the company's compensation policy, provided that the compensation committee and, thereafter, the board of directors approve such terms, based on, among other things, the considerations and mandatory requirements set forth in the Companies Law. Following such approval by the compensation committee and board of directors, shareholder approval would be required.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval, in the same manner described above, is required once every three years, unless, with respect to extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

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, voting at general meetings of shareholders on the following matters:

- an amendment to the articles of association;

- an increase in the company's authorized share capital;

- a merger; and

- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

The remedies generally available upon a breach of contract will also apply to a breach of the above-mentioned duties, 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 has another power with respect to a company, is under a duty to act with fairness towards the company. The Companies Law does not describe the substance of this duty except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness, taking the shareholder's position in the company into account.

Exculpation, insurance and indemnification of office holders

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our Articles of Association include such a provision. An Israeli company may not exculpate a director from liability arising out of a prohibited dividend or distribution to shareholders.

An Israeli company may indemnify an office holder in respect of the following liabilities and expenses incurred for acts performed as an office holder, either in advance of an event or following an event, provided a provision authorizing such indemnification is contained in its articles of association:

- financial liability imposed on him or her in favor of another person pursuant to a judgment, 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 events and amount or criteria;

- reasonable litigation expenses, including 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 (1) no indictment was filed against such office holder as a result of such investigation or proceeding; and (2) no financial liability, such as a criminal penalty, 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; 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 Israeli company may insure an office holder against the following liabilities incurred for acts performed as an office holder if and to the extent provided in the company's articles of association:

- a breach of duty of loyalty to the company, to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;

- a breach of duty of care to the company or to a third party, including a breach arising out of the negligent (but not grossly negligent) conduct of the office holder; and

- a financial liability imposed on the office holder in favor of a third party.

An Israeli company may not indemnify or insure an office holder against any of the following, and any provision in a company's articles of association which allows for any of the following is invalid:

- a breach of duty of loyalty, except 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 or forfeit levied against the office holder.

Under the Companies Law and the regulations promulgated thereunder, exculpation, indemnification and insurance of office holders must be approved by the compensation committee and the board of directors and must be provided in accordance with the Company's Compensation Policy duly adopted by the shareholders.

An amendment to the Israeli Securities Law and a corresponding amendment to the Companies Law authorize the ISA to impose administrative sanctions against companies like ours, and their office holders for certain violations of the Israeli Securities Law or the Companies Law. These sanctions include monetary sanctions and certain restrictions on serving as a director or senior officer of a public company for certain periods of time. The amendments to the Israeli Securities Law and to the Companies Law provide that only certain types of such liabilities may be reimbursed by indemnification and insurance. Specifically, legal expenses (including attorneys' fees) incurred by an individual in the applicable administrative enforcement proceeding and certain compensation payable to injured parties for damages suffered by them are permitted to be reimbursed via indemnification or insurance, provided that such indemnification and insurance are authorized by the company's articles of association and receive the requisite corporate approvals.

Our Articles of Association allow us to indemnify and insure our office holders for any liability imposed on them as a consequence of an act (including any omission) which was performed by virtue of being an office holder. In November 2011, our shareholders approved (i) the amendment of our Articles of Association to authorize indemnification and insurance in connection with administrative enforcement proceedings, including without limitation, the specific amendments to the Israeli Securities Law and the Companies Law described above and (ii) a new form of indemnification letter for our directors and officers so as to reflect the amendment to our Articles of Association, which new form of letter was also approved in October 2011 by our Audit Committee and Board of Directors, and in November 2011 by our shareholders. The terms of such agreements are consistent with the provisions of the Compensation Policy which was approved by our shareholders in July 2019, as amended by our shareholders in March 2020 and April 2021.

Our office holders are currently covered by a directors' and officers' liability insurance policy. The terms of such directors' and officers' insurance are consistent with the provisions of the Compensation Policy which was approved by our shareholders in July 2019, as amended by our shareholders in March 2020 and April 2021. The Compensation Policy authorizes us to purchase insurance policies (including run-off policies) to cover the liability of directors and office holders that are in office at such time and that shall be in office from time to time, including directors and office holders that may have a controlling interest in the Company. Such insurance policies are authorized within the following limits: (1) the premium for each policy period shall not exceed $550,000, (2) the maximum aggregate limit of liability pursuant to the policies shall not exceed $20 million for each insurance period, and (3) the maximum deductible shall not exceed $250,000. In addition, the Compensation Committee is authorized to increase the coverage purchased and/or the premium paid for such policies by up to 30% in any year, as compared to the previous year, or cumulatively for a number of years, without an additional shareholders' approval to the extent permitted under the Companies Law. See also "Related Party Transactions — Indemnification Agreements."

As of the date of this Annual Report on Form 20-F, no claims have been filed under our directors' and officers' liability insurance policy, there is no pending litigation or proceeding against any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

For significant ways in which our corporate governance practices differ from those required by the Nasdaq Rules, see "Item 16G. Corporate Governance."

D. Employees

As of December 31, 2021, we had 38 employees, all of whom are employed in Israel. Of our employees, 14 hold M.D. or Ph.D. degrees.

	December 31,		
	2019	2020	2021
Management and administration	10	9	9
Research and development	30	27	27
Sales and marketing	2	2	2
Total	42	38	38

While none of our employees are party to any collective bargaining agreements, 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) which are applicable to our employees by virtue of expansion orders issued in accordance with relevant labor laws by the Israel 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 expansion orders which apply to our employees principally concern the requirement for length of the workday and work week, mandatory contributions to a pension fund, annual recreation allowance, travel expenses payment and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

We have never experienced any employment-related work stoppages and believe our relationship with our employees is good.

E. Share Ownership

The following table sets forth information regarding the beneficial ownership of our outstanding ordinary shares as of March 15, 2022 of each of our directors and executive officers individually and as a group.

	Number of Ordinary Shares Beneficially Held	Percent of Class
Directors		
Aharon Schwartz[1]	2,168,333	*
Michael J. Anghel[2]	413,333	*
Nurit Benjamini[3]	403,333	*
B.J. Bormann[4]	413,333	*
Raphael Hofstein[5]	413,333	*
Avraham Molcho[6]	403,333	*
Sandra Panem[7]	413,333	*
Executive officers		
Philip A. Serlin[8]	4,093,647	*
Mali Zeevi[9]	1,486,427	*
Ella Sorani[10]	1,290,302	*
Abi Vainstein-Haras[11]	1,497,502	*
All directors and executive officers as a group (11 persons)[12]	12,996,209	1.56%

* Less than 1.0%.

(1) Includes 413,333 ordinary shares issuable upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 46,667 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2022.

(2) Includes 413,333 ordinary shares issuable upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 46,667 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2022.

(3) Includes 403,333 ordinary shares issuable upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 46,667 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2022.

(4) Includes 413,333 ordinary shares issuable upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 46,667 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2022.

(5) Includes 413,333 ordinary shares issuable upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 46,667 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2022.

(6) Includes 403,333 ordinary shares issuable upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 46,667 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2022.

(7) Includes 413,333 ordinary shares issuable upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 46,667 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2022.

(8) Includes 3,921,729 issued ordinary shares upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 4,920,107 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 15, 2022.

(9) Includes 1,249,310 ordinary shares issuable upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 1,138,123 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 15, 2022.

(10) Includes 1,224,152 ordinary shares issuable upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 1,138,123 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 15, 2022.

(11) Includes 1,414,752 ordinary shares issuable upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 1,138,123 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 15, 2022.

(12) Includes 10,683,274 ordinary shares issuable upon exercise of outstanding options within 60 days of March 15, 2022. Does not include 8,661,145 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 15, 2022.

Change in Control

To our knowledge, (i) we are not directly or indirectly owned or controlled by another corporation, by any foreign government or by any other natural or legal person severally or jointly, except as disclosed in the above table regarding our major shareholders, and (ii) there are no arrangements which would result in our change in control at a subsequent date.

Significant Changes in the Ownership of Major Shareholders

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

Major Shareholders Voting Rights

Our major shareholders do not have different voting rights.

Record Holders

Bank of New York Mellon, or BNY, is the holder of record for the Company's American Depositary Receipt program, pursuant to which each ADS represents 15 ordinary shares. As of March 15, 2022, BNY held 625,171,826 ordinary shares representing 87.4% of our issued share capital held 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.

Equity Compensation Plan

2003 Share Incentive Plan

In 2003, we adopted the BioLineRx Ltd. 2003 Share Incentive Plan, or the Plan. The Plan provides for the granting of options, ordinary shares, restricted stock units and performance stock units to our directors, employees, consultants and service providers, and to the directors, employees, consultants and service providers of our subsidiaries and affiliates. The Plan provides for equity grants to be made at the determination of our Board of Directors in accordance with applicable law. As of March 15, 2022, there were 43.7 million ordinary shares issuable upon the exercise of outstanding equity grants under the Plan.

In August 2013, our Board of Directors approved amendments to the Plan to take into account changes in laws and regulations that had occurred since its adoption and to extend the term of the plan until November 2023. In January 2016, our Board of Directors approved amendments to the Plan in order to permit the granting of restricted stock units, or RSUs, and performance stock units, or PSUs, to eligible grantees.

From time to time, our Board of Directors has approved an increase in the number of shares reserved for the purpose of equity grants pursuant to the Plan. As of March 15, 2022, the number of shares so reserved was 5.6 million.

Administration of Our Plan

Our Plan is administered by our Board of Directors for the purposes of making equity grants and approving the terms of those grants, including, in the case of options, exercise price, method of payment, vesting schedule, acceleration of vesting and the other matters necessary in the administration of these plans. Equity grants made under the Plan to eligible employees and office holders are made under Section 102 of the Israel Income Tax Ordinance pursuant to which the securities granted must be allocated or issued to a trustee and be held in trust for two years from the date upon which such grant was made, provided that securities granted prior to January 1, 2006, or the ordinary shares issued upon exercise of options, are subject to being held in trust for two years from the end of the year in which the securities are granted. Under Section 102, any tax payable by an employee from the grant of securities or the exercise of options is deferred until the transfer of the securities (or ordinary shares issued upon the exercise of options) by the trustee to the employee or upon the sale of the securities or ordinary shares, as the case may be, and gains may qualify to be taxed as capital gains at a rate equal to 25%, subject to compliance with specified conditions.

Options granted under the Plan generally vest over four years, and they expire 10 years from the grant date. If we terminate an employee for cause, all of the employee's vested and unvested options expire immediately from the time of delivery of the notice of discharge, unless determined otherwise by the Audit Committee or the Board of Directors. Upon termination of employment for any other reason, including due to death or disability of the employee, vested options may be exercised within three months of the termination date, unless otherwise determined by the Compensation Committee or the Board of Directors. Vested options which are not exercised and unvested options return to the pool of reserved ordinary shares under the Plan for reissuance. The right to receive ordinary shares pursuant to PSUs granted under the Plan will vest upon the achievement by BioLineRx of certain performance goals to be established by the Board of Directors.

In the event of a merger, consolidation, reorganization or similar transaction or our voluntary liquidation or dissolution, all of our unexercised vested equity grants and any unvested equity grants will be automatically terminated. However, in the event of a change of control, or merger, consolidation, reorganization or similar transaction resulting in the acquisition of at least 50% of our voting power, or the sale or transfer of all or substantially all of our outstanding shares assets, the equity grants then outstanding may be assumed or substituted for an appropriate number of shares of each class of shares or other securities and/or assets of the successor company in such transaction (or a parent or subsidiary or another affiliate of such successor company) as were distributed to our shareholders in respect of the transaction. In addition to the foregoing, our Board of Directors has approved the inclusion in the option agreements of the Company's officers of a provision for accelerated vesting of options if both a change of control of the Company occurs and, following such change of control, the officer's employment is terminated or there is a significant demotion in the officer's new job or position.

To our knowledge the significant changes in the percentage of ownership held by our major shareholders reported in our Annual Reports on Form 20-F during the past three have been the decrease in 2020 below 5% in the percentage ownership held by BVF Partners L.P. and Senvest Management, LLC.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

Except as set forth in "Item 6. Directors, Senior Management and Employees—E. Share Ownership," to the best of our knowledge, no other person who we know beneficially owns 5.0% or more of the Company's ordinary shares outstanding as of March 15, 2022.

B. Related Party Transactions

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 — Compensation of Directors and Senior Management."

Indemnification Agreements

Our Articles of Association and Compensation Policy approved by our shareholders permit us to exculpate, indemnify and insure our directors and office holders to the fullest extent permitted by the Companies Law. We have entered into agreements with each of our office holders undertaking to indemnify them to the fullest extent permitted by law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance. We have obtained directors' and officers' insurance for each of our officers and directors. See "Item 6. Directors, Senior Management and Employees — Board Practices — Exculpation, insurance and indemnification of office holders."

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and other Financial Information

See "Item 18. Financial Statements."

Legal Proceedings

We are not involved in any material legal proceedings.

Dividend Distributions

We have never declared or paid cash dividends to our shareholders. Currently we do not intend to pay cash dividends. We currently intend to reinvest any future earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our Board of Directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, applicable Israeli law and other factors our Board of Directors may deem relevant.

B. Significant Changes

None.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ADSs have been trading on Nasdaq under the symbol "BLRX" since July 2011. Our ordinary shares have been trading on the TASE under the symbol "BLRX" since February 2007.

B. Plan of Distribution

Not applicable.

C. Markets

Our ADSs trade on Nasdaq under the symbol "BLRX." Our ordinary shares trade on the TASE under the symbol "BLRX."

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. Articles of Association

A copy of our Articles of Association is attached as Exhibit 2.1 to this Annual Report. Other than as disclosed below, the information called for by this Item is set forth in Exhibit 2.2 to this Annual Report and is incorporated by reference into this Annual Report.

C. Material Contracts

For a discussion of our out-licensing and in-licensing agreements, see "Item 4. Information on the Company." The following are summary descriptions of certain other material contracts to which we are a party. The descriptions provided below do not purport to be complete and are qualified in their entirety by the complete agreements, which are attached as exhibits to this Annual Report on Form 20-F.

Clinical Trial Collaboration and Supply Agreement with MSD

In January 2016, we entered into a clinical collaboration agreement with MSD, to support a Phase 2 study investigating our motixafortide in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic cancer. The Phase 2 study will evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T-cells into the tumor and their reactivity. According to the terms of the agreement, we are sponsoring and performing the study, which was initiated in September 2016, and MSD is supplying its compound for purposes of the study. The parties have agreed on the establishment of a joint development committee which has the responsibility of coordinating all regulatory and other activities under the agreement.

In July 2018, the collaboration agreement with MSD was amended in light of the parties' agreement to expand the study under the collaboration to include a triple combination arm investigating the safety, tolerability and efficacy of motixafortide, KEYTRUDA and chemotherapy. See "Item 4 — Information on the Company — Business Overview — Therapeutic Candidates — motixafortide." Upon completion of the study, or at any earlier point, both parties have the option to expand the collaboration to include a pivotal registration study.

Loan Agreement with Kreos Capital

In October 2018, we entered into a loan agreement with Kreos Capital. The purpose of the loan was to finance the $10 million payment made by the Company to Biokine as part of the consideration for amending the license agreement for motixafortide. See "Item 4. Information on the Company — Business Overview — In-Licensing Agreements — motixafortide." The loan had a 12-month interest-only period, which concluded in September 2019, followed by a 36-month repayment period beginning in October 2019. Borrowings under the loan will bear interest at a fixed rate of 9.5% per annum. As security for the loan, Kreos Capital received a first-priority, secured interest in all Company assets, including intellectual property. In connection with providing the loan, Kreos Capital received a warrant to purchase 63,837 ADSs at an exercise price of $14.10 per ADS. The warrant is exercisable for a period of ten years from the date of issuance.

D. Exchange Controls

There are no Israeli government laws, decrees or regulations that restrict or that affect our export or import of capital or the remittance of dividends, interest or other payments to non-resident holders of our securities, including the availability of cash and cash equivalents for use by us and our wholly-owned subsidiaries, except or otherwise as set forth under "Item 10E. Additional Information — Taxation."

E. Taxation

The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our ordinary shares or ADSs, both referred to in this Item 10E as the ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, non-U.S., including Israeli, or other taxing jurisdiction.

Israeli Tax Considerations

The following is a summary of the material Israeli tax laws applicable to us. This section also contains a discussion of material Israeli tax consequences concerning the ownership and disposition of our shares. 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 residents of Israel or traders in securities who are subject to special tax regimes not covered in this discussion. Because certain parts of this discussion are based on new tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion.

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax on their taxable income. The regular corporate tax rate in Israel is 23% for the year 2018 and thereafter. Capital gains derived by an Israeli company are now generally subject to tax at the same rate as the corporate tax rate.

Under amendment no. 73 to the Encouragement of Capital Investment Law, a portion of the Company's taxable income in Israel is entitled to a preferred 12% tax rate on its income derived from intellectual property. As of December 31, 2021, the tax loss carryforwards of BioLineRx were approximately $325 million. The tax loss carryforwards have no expiration date.

Taxation of Israeli Individual Shareholders on Receipt of Dividends. Israeli residents who are individuals are generally subject to Israeli income tax for dividends paid on our ordinary shares (other than bonus shares or share dividends) at a rate of either 25% or 30%, if the recipient of such dividend is a substantial shareholder (as defined below) at the time of distribution or at any time during the preceding 12-month period.

Taxation of Israeli Resident Corporations on Receipt of Dividends. Israeli resident corporations are generally exempt from Israeli corporate tax for dividends paid on our ordinary shares.

Taxation of Non-Israeli Shareholders on Receipt of Dividends. Non-residents of Israel (individuals or corporations) are generally subject to Israeli income tax on the receipt of dividends paid on our ordinary shares at the rate of 25% (or 30% if such person is a "substantial shareholder" at the time receiving the dividend or on any date in the 12 months preceding such date), which tax will be withheld at the source, unless a lower rate is provided in a tax treaty between Israel and the shareholder's country of residence and subject to the receipt in advance of a valid certificate from the Israeli Tax Authorities.

Under the U.S.-Israel Tax Treaty, Israeli withholding tax on dividends paid to a U.S. resident for treaty purposes may not, in general, exceed 25. Where the recipient is a U.S. corporation owning 10% or more of the voting stock of the paying corporation during the part of the paying corporation's taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any) and the dividend is not paid from the profits of a Benefited Enterprise, the Israeli tax withheld may not exceed 12.5%, subject to certain conditions.

A "substantial shareholder" is generally a person who alone, or together with his relative or another person who collaborates with him on a regular basis, holds, directly or indirectly, at least 10% of any of the "means of control" of the corporation. "Means of control" generally include the right to vote, receive profits, nominate a director, a general manager of the company or holders of similar offices in other bodies of persons, receive assets upon liquidation, or instruct someone who holds any of the aforesaid rights regarding the manner in which he or she is to exercise such right(s), and all regardless of the source of such right.

A non-resident of Israel who receives dividends from which tax was withheld is generally exempt from the duty to file returns in Israel in respect of such income, provided that: (1) such income was not derived from a business conducted in Israel by the taxpayer (2) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed and (3) the taxpayer is not obliged to pay excess tax.

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.

Taxation of Capital Gains. Israeli law 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 assets located in Israel, including shares in Israeli companies, by non-residents of Israel, unless a specific exemption is available or unless a tax treaty between Israel and the shareholder's country of residence provides otherwise and subject to the receipt in advance of a valid certificate from the Israeli Tax Authorities. The law distinguishes between real capital gain and inflationary surplus. The inflationary surplus is a portion of the total capital gain that is equivalent to the increase of the relevant asset's purchase price which is attributable to the increase in the Israeli consumer price index or, in certain circumstances, a foreign currency exchange rate, between the date of purchase and the date of sale. The real capital gain is the excess of the total capital gain over the inflationary surplus.

Capital Gains Taxes Applicable to Israeli Resident Shareholders. An individual is subject to a tax at a rate of 25% on real capital gains derived from the sale of shares, as long as the individual is not a substantial shareholder at the time of sale or at any time during the 12-month period preceding the company's issuance of the shares.

An individual who is a substantial shareholder at the time of sale or at any time during the preceding 12-month period is subject to tax at a rate of 30% in respect of real capital gains derived from the sale of shares issued by the company in which he or she is a substantial shareholder.

Capital Gains Taxes Applicable to Non-Israeli Resident Shareholders. Shareholders that are not Israeli residents are generally exempt from Israeli capital gains tax on any gains derived from the sale, exchange or disposition of our ordinary shares, provided that such shareholders did not acquire their ordinary shares prior to our initial public offering on the TASE and such gains were not derived from a permanent establishment or business activity of such shareholders in Israel. However, non-Israeli corporations will not be entitled to the foregoing exemptions if one or more Israeli residents (a) have a controlling interest of more than 25% in such non-Israeli corporation or (b) are the beneficiaries of or are entitled to 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly.

In addition, under the U.S.-Israel Tax Treaty, the sale, exchange or disposition of our ordinary shares by a shareholder who is a U.S. resident (for purposes of the U.S.-Israel Tax Treaty) holding the ordinary shares as a capital asset is exempt from Israeli capital gains tax unless (1) the shareholder holds, directly or indirectly, shares representing 10% or more of our voting capital during any part of the 12-month period preceding such sale, exchange or disposition; (2) the capital gains arising from such sale are attributable to a permanent establishment of the shareholder located in Israel; (3) a shareholder who is an individual is present in Israel for a period or periods aggregating 183 days or more during a taxable year. In either case, the sale, exchange or disposition of ordinary shares would be subject to Israeli tax, to the extent applicable (subject to the receipt in advance of a valid certificate from the Israeli tax authorities); however, under the U.S.-Israel Tax Treaty, the U.S. resident would be permitted to claim a credit for the tax against the U.S. federal income tax imposed with respect to the sale, exchange or disposition, subject to the limitations in U.S. laws applicable to foreign tax credits. The U.S.-Israel Tax Treaty does not relate to U.S. state or local taxes.

Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale.

The purchaser, the Israeli stockbrokers or financial institution through which the shares are held are obliged, subject to the above mentioned exemptions, to withhold tax upon the sale of securities on the amount of the consideration paid upon the sale of the securities (or on the Real Capital Gain realized on the sale, if known), at the rate of 25% in respect of an individual or at a corporate rate in respect of a corporation (23%).

Upon the sale of securities traded on a stock exchange, a detailed return, including a computation of the tax due, must be filed and an advance payment must be paid on January 31 and July 31 of every tax year in respect of sales of securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Israel Income Tax Ordinance and regulations promulgated thereunder, the aforementioned return need not be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax returns.

Excess Tax. Individuals who are subject to tax in Israel (whether such individual is an Israeli resident or non-Israeli resident) are also subject to an additional tax at a rate of 3% on annual income exceeding NIS 663,240 for 2022 and thereafter, which amount is linked to the annual change in the Israeli consumer price index), including, but not limited to, dividends, interest and capital gains.

U.S. Federal Income Tax Considerations

The following is a general summary of certain material U.S. federal income tax considerations relating to the purchase, ownership and disposition of our ordinary shares and ADSs by U.S. Investors (as defined below) that are initial purchasers of such ordinary shares or ADSs and that hold such ordinary shares or ADSs as capital assets for U.S. federal income tax purposes (generally, property held for investment). This summary is based on the Internal Revenue Code of 1986, as amended, or the Code, the regulations of the U.S. Department of the Treasury issued pursuant to the Code, or the Treasury Regulations, and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect, or to different interpretation. No ruling has been sought from the IRS with respect to any U.S. federal income tax consequences described below, and there can be no assurance that the IRS or a court will not take a contrary position. This summary is for general information only and does not address all of the tax considerations that may be relevant to specific U.S. Investors in light of their particular circumstances or to U.S. Investors subject to special treatment under U.S. federal income tax law (such as, without limitation, banks, insurance companies, tax-exempt entities, retirement plans, regulated investment companies, partnerships, dealers in securities, brokers, real estate investment trusts, certain former citizens or residents of the United States, persons who acquire our ordinary shares or ADSs as part of a straddle, hedge, conversion transaction or other integrated investment, persons that have a "functional currency" other than the Dollar, persons that own (or are deemed to own, indirectly or by attribution) 10% or more of our ordinary shares or ADSs (by vote or value), persons subject to special tax accounting rules under section 451(b), or persons that generally mark their securities to market for U.S. federal income tax purposes). This summary does not address any U.S. state or local or non-U.S. tax considerations, any U.S. federal estate, gift or alternative minimum tax considerations or any additional U.S. federal tax consequences other than U.S. federal income tax consequences.

As used in this summary, the term "U.S. Investor" means a beneficial owner of our ordinary shares or ADSs that is, for U.S. federal income tax purposes, (i) an individual citizen or resident of the United States, (ii) a corporation, or other entity taxable 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 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 a trust that has validly elected to be treated as a U.S. person for U.S. federal income tax purposes, whose status as a U.S. person is not overwritten by an applicable tax treaty.

If an entity treated as a partnership for U.S. federal income tax purposes holds our ordinary shares or ADSs, the tax treatment of such entity and each person treated as a partner thereof will generally depend upon the status and activities of the entity and such person. An investor that is treated as a partnership for U.S. federal income tax purposes should consult its own tax advisor regarding the U.S. federal income tax considerations applicable to it and its partners of the purchase, ownership and disposition of its ordinary shares or ADSs.

Prospective investors should be aware that this summary does not address the tax consequences to investors who are not U.S. Investors. Prospective investors should consult their own tax advisors as to the particular tax considerations applicable to them relating to the purchase, ownership and disposition of their ordinary shares or ADSs, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Taxation of U.S. Investors

The discussions under "— Distributions," and under "— Sale, Exchange or Other Disposition of Ordinary Shares or ADSs" below assumes that we will not be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. However, we have not determined whether we will be a PFIC for the taxable year ending December 31, 2022, and it is possible that we will be a PFIC for the taxable year ending December 31, 2022 or in any subsequent year. For a discussion of the rules that would apply if we are treated as a PFIC, see the discussion under "— Passive Foreign Investment Company."

Distributions. We have no current plans to pay dividends. To the extent we pay any dividends, a U.S. Investor will be required to include in gross income as a taxable dividend the amount of any distributions made on the ordinary shares or ADSs, including the amount of any Israeli taxes withheld, when actually or constructively received, to the extent that those distributions are paid out of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Any distributions in excess of our earnings and profits will be applied against and will reduce the U.S. Investor's tax basis in its ordinary shares or ADSs and to the extent they exceed that tax basis, will be treated as gain from the sale or exchange of those ordinary shares or ADSs. We do not intend to calculate our earnings and profits under U.S. federal income tax principles. Therefore, a U.S. Investor should expect that a distribution will be treated as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. If we were to pay dividends to holders of our ordinary shares, we expect to pay such dividends in NIS; however, dividends paid to holders of our ADSs will be paid in dollars. A dividend paid in NIS, including the amount of any Israeli taxes withheld, will be includible in a U.S. Investor's income as a dollar amount calculated by reference to the exchange rate in effect on the date such dividend is received, regardless of whether the payment is in fact converted into dollars. If the dividend is converted to dollars on the date of receipt, a U.S. Investor generally will not recognize a foreign currency gain or loss. However, if the U.S. Investor converts the NIS into dollars on a later date, the U.S. Investor must include, in computing its income, any gain or loss resulting from any exchange rate fluctuations. The gain or loss will be equal to the difference between (i) the dollar value of the amount included in income when the dividend was received and (ii) the amount received on the conversion of the NIS into dollars. Such gain or loss will generally be ordinary income or loss and United States source for U.S. foreign tax credit purposes. U.S. Investors should consult their own tax advisors regarding the tax consequences to them if we pay dividends in NIS or any other non-U.S. currency.

Subject to certain significant conditions and limitations, including potential limitations under the United States-Israel income tax treaty, any Israeli taxes paid on or withheld from distributions from us and not refundable to a U.S. Investor may be credited against the investor's U.S. federal income tax liability or, alternatively, may be deducted from the investor's taxable income. This election is made on a year-by-year basis and applies to all foreign taxes paid by a U.S. Investor or withheld from amounts paid to a U.S. Investor that year. Dividends paid on the ordinary shares or ADSs generally will constitute income from sources outside the United States and be categorized as "passive category income" or, in the case of some U.S. Investors, as "general category income" for U.S. foreign tax credit purposes.

Since the rules governing foreign tax credits are complex, U.S. Investors should consult their own tax advisor regarding the availability of foreign tax credits in their particular circumstances.

Dividends paid on the ordinary shares and ADSs will not be eligible for the "dividends-received" deduction generally allowed to corporate U.S. Investors with respect to dividends received from U.S. corporations.

Distributions treated as dividends that are received by an individual U.S. Investor from "qualified foreign corporations" generally qualify for a reduced maximum tax rate so long as certain holding period and other requirements are met. A non-U.S. corporation (other than a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (i) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information program, or (ii) with respect to any dividend it pays on stock which is readily tradable on an established securities market in the United States. Any dividend paid by us in a taxable year in which we are a PFIC (or with respect to which we were a PFIC in the preceding taxable year) will be subject to tax at regular ordinary income rates. As mentioned above, we believe we were not a PFIC for our 2021 taxable year and have not determined whether we will be a PFIC for our 2022 taxable year. U.S. Investors should consult their own tax advisors regarding the availability of the lower rate for dividends paid with respect to our ordinary shares and ADSs.

The additional 3.8% Medicare tax (described below) may apply to dividends received by certain U.S. Investors who meet certain modified adjusted gross income thresholds.

Sale, Exchange or Other Disposition of Ordinary Shares and ADSs. Subject to the discussion under "— Passive Foreign Investment Company" below, a U.S. Investor generally will recognize capital gain or loss upon the sale, exchange or other taxable disposition of ordinary shares or ADSs in an amount equal to the difference between the amount realized on the sale, exchange or other taxable disposition and the U.S. Investor's adjusted tax basis in such ordinary shares or ADSs. This capital gain or loss will be long-term capital gain or loss if the U.S. Investor's holding period in the ordinary shares or ADSs exceeds one year. Preferential tax rates for long-term capital gain will apply to individual U.S. Investors. The deductibility of capital losses is subject to limitations. The gain or loss will generally be income or loss from sources within the United States for U.S. foreign tax credit purposes, subject to certain possible exceptions under the U.S.-Israel Tax Treaty. The additional 3.8% Medicare tax (described below) may apply to gains recognized upon the sale, exchange, or other taxable disposition of our ordinary shares or ADSs by certain U.S. Investors who meet certain modified adjusted gross income thresholds.

U.S. Investors should consult their own tax advisors regarding the U.S. federal income tax consequences of receiving currency other than Dollars upon the disposition of ordinary shares or ADSs.

Medicare Tax. In addition, certain U.S. persons, including individuals, estates and trusts, will be subject to an additional 3.8% Medicare tax, or net investment income tax, on unearned income. For individuals, the additional Medicare tax applies to the lesser of (i) "net investment income" or (ii) the excess of "modified adjusted gross income" over $200,000 ($250,000 if married and filing jointly or $125,000 if married and filing separately). "Net investment income" generally equals the taxpayer's gross investment income reduced by the deductions that are allocable to such income. Investment income generally includes passive income such as interest, dividends, annuities, royalties, rents, and capital gains. U.S. Investors are urged to consult their own tax advisors regarding the implications of the additional Medicare tax resulting from their ownership and disposition of ordinary shares or ADSs.

Passive Foreign Investment Company

In general, a corporation organized outside the United States 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 its gross income is "passive income" or (ii) on average at least 50% of its assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in the public offering. Assets that produce or are held for the production of passive income may include cash, even if held as working capital or raised in a public offering, as well as marketable debt securities and other assets that may produce passive income. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Under the tests described above, whether or not we are a PFIC will be determined annually based upon the composition of our income and the composition and valuation of our assets, all of which are subject to change.

We believe that we were a PFIC for U.S. federal income tax purposes for taxable years ended prior to December 31, 2009 and for taxable years ended December 31, 2011, 2012 and 2014 through 2019. We believe we were not a PFIC for taxable years ended 2009, 2010, 2013, 2020 and 2021, and we have not determined whether we will be a PFIC for the taxable year ending December 31, 2022. Because the PFIC determination is highly fact intensive and made at the end of each taxable year, there can be no assurance that we will not be a PFIC for taxable year ending December 31, 2022 or in any subsequent year. Upon request, we intend to annually inform U.S. Investors if we and any of our subsidiaries were a PFIC with respect to the preceding year.

U.S. Investors should be aware of certain tax consequences of investing directly or indirectly in us if we are a PFIC. A U.S. Investor is subject to different rules depending on whether the U.S. Investor makes an election to treat us as a "qualified electing fund," known as a QEF election, for the first taxable year that the U.S. Investor holds ordinary shares or ADSs, which is referred to in this disclosure as a "timely QEF election," makes a "mark-to-market" election with respect to the ordinary shares or ADSs (if such election is available) or makes neither election.

QEF Election. A U.S. Investor who makes a timely QEF election, referred to in this disclosure as an "Electing U.S. Investor," with respect to us must report for U.S. federal income tax purposes his pro rata share of our ordinary earnings and net capital gain, if any, for our taxable year that ends with or within the taxable year of the Electing U.S. Investor. The "net capital gain" of a PFIC is the excess, if any, of the PFIC's net long-term capital gains over its net short-term capital losses. The amount so included in income generally will be treated as ordinary income to the extent of such Electing U.S. Investor's allocable share of the PFIC's ordinary earnings and as long-term capital gain to the extent of such Electing U.S. Investor's allocable share of the PFIC's net capital gains. Such Electing U.S. Investor generally will be required to translate such income into Dollars based on the average exchange rate for the PFIC's taxable year with respect to the PFIC's functional currency. Such income generally will be treated as income from sources outside the United States for U.S. foreign tax credit purposes. Amounts previously included in income by such Electing U.S. Investor under the QEF rules generally will not be subject to tax when they are distributed to such Electing U.S. Investor. The Electing U.S. Investor's tax basis in ordinary shares or ADSs generally will increase by any amounts so included under the QEF rules and decrease by any amounts not included in income when distributed.

An Electing U.S. Investor will be subject to U.S. federal income tax on such amounts for each taxable year in which we are a PFIC, regardless of whether such amounts are actually distributed to such Electing U.S. Investor. However, an Electing U.S. Investor 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 an Electing U.S. Investor is an individual, any such interest will be treated as non-deductible "personal interest."

Any net operating losses or net capital losses of a PFIC will not pass through to the Electing U.S. Investor and will not offset any ordinary earnings or net capital gain of a PFIC recognized by Electing U.S. Investors in subsequent years.

So long as an Electing U.S. Investor's QEF election with respect to us is in effect with respect to the entire holding period for ordinary shares or ADSs, any gain or loss recognized by such Electing U.S. Investor on the sale, exchange or other disposition of such ordinary shares or ADSs generally will be long-term capital gain or loss if such Electing U.S. Investor has held such ordinary shares or ADSs for more than one year at the time of such sale, exchange or other disposition. Preferential tax rates for long-term capital gain will apply to individual U.S. Investors. The deductibility of capital losses is subject to limitations.

A U.S. Investor makes a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. A QEF election generally may not be revoked without the consent of the IRS. Upon request, we intend to annually furnish U.S. Investors with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. Investor) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC. A QEF election will not apply to any taxable year during which we are not a PFIC but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Each U.S. Investor is encouraged to consult its own tax advisor with respect to tax consequences of a QEF election with respect to us.

Mark-to-Market Election. Alternatively, if our ordinary shares or ADSs are treated as "marketable stock," a U.S. Investor would be allowed to make a "mark-to-market" election with respect to our ordinary shares or ADSs, provided the U.S. Investor completes and files IRS Form 8621 in accordance with the relevant instructions and related Treasury Regulations. If that election is made, the U.S. Investor generally would include as ordinary income in each taxable year the excess, if any, of the fair market value of the ordinary shares or ADSs at the end of the taxable year over such investor's adjusted tax basis in the ordinary shares or ADSs. Thus, the U.S. Investor may recognize taxable income without receiving any cash to pay its tax liability with respect to such income. The U.S. Investor would also be permitted an ordinary loss in respect of the excess, if any, of the U.S. Investor's adjusted tax basis in the ordinary shares or ADSs over their fair market value at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. A U.S. Investor's tax basis in the ordinary shares or ADSs would be adjusted to reflect any such income or loss amount. Gain realized on the sale, exchange or other disposition of the ordinary shares or ADSs would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of the ordinary shares or ADSs would be treated as ordinary loss to the extent that such loss does not exceed the net mark-to-market gains previously included in income by the U.S. Investor, and any loss in excess of such amount will be treated as capital loss. Amounts treated as ordinary income will not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains.

Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable Treasury Regulations. A class of stock is regularly traded on an exchange during any calendar year during which such class of stock is traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. To be marketable stock, our ordinary shares or ADSs must be regularly traded on a qualifying exchange (i) in the United States that is registered with the SEC or a national market system established pursuant to the Exchange Act or (ii) outside the United States that is properly regulated and meets certain trading, listing, financial disclosure and other requirements. A mark-to-market election will not apply to our ordinary shares or ADSs held by a U.S. Investor for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC unless our ordinary shares or ADSs cease to be marketable. A mark-to-market election generally may not be revoked without the consent of the IRS. Such election will not apply to any PFIC subsidiary that we own. Each U.S. Investor is encouraged to consult its own tax advisor with respect to the availability and tax consequences of a mark-to-market election with respect to our ordinary shares or ADSs.

Default PFIC Rules. A U.S. Investor who does not make a timely QEF election or a mark-to-market election, referred to in this disclosure as a "Non-Electing U.S. Investor," will be subject to special rules with respect to (a) any "excess distribution" (generally, the portion of any distributions received by the Non-Electing U.S. Investor on the ordinary shares or ADSs in a taxable year in excess of 125% of the average annual distributions received by the Non-Electing U.S. Investor in the three preceding taxable years, or, if shorter, the Non-Electing U.S. Investor's holding period for the ordinary shares or ADSs), and (b) any gain realized on the sale or other disposition of such ordinary shares or ADSs. Under these rules:

- the excess distribution or gain would be allocated ratably over the Non-Electing U.S. Investor's holding period for the ordinary shares or ADSs;
- the amount allocated to the current taxable year and any year prior to us becoming a PFIC would be taxed as ordinary income; and
- the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year.

If a Non-Electing U.S. Investor who is an individual dies while owning our ordinary shares or ADSs, the Non-Electing U.S. Investor's successor would be ineligible to receive a step-up in tax basis of the ordinary shares or ADSs. Non-Electing U.S. Investors are encouraged to consult their tax advisors regarding the application of the PFIC rules to their specific situation.

A Non-Electing U.S. Investor who wishes to make a QEF election for a subsequent year may be able to make a special "purging election" pursuant to Section 1291(d) of the Code. Pursuant to this election, a Non-Electing U.S. Investor would be treated as selling his or her ordinary shares or ADSs for fair market value on the first day of the taxable year for which the QEF election is made. Any gain on such deemed sale would be subject to tax under the rules for Non-Electing U.S. Investors as discussed above. Non-Electing U.S. Investors are encouraged to consult their tax advisors regarding the availability of a "purging election" as well as other available elections.

To the extent a distribution on our ordinary shares or ADSs does not constitute an excess distribution to a Non-Electing U.S. Investor, such Non-Electing U.S. Investor generally will be required to include the amount of such distribution in gross income as a dividend to the extent of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) that are not allocated to excess distributions. The tax consequences of such distributions are discussed above under "— Taxation of U.S. Investors — Distributions." Each U.S. Investor is encouraged to consult its own tax advisor with respect to the appropriate U.S. federal income tax treatment of any distribution on our ordinary shares or ADSs.

If we are treated as a PFIC for any taxable year during the holding period of a Non-Electing U.S. Investor, we will continue to be treated as a PFIC for all succeeding years during which the Non-Electing U.S. Investor is treated as a direct or indirect Non-Electing U.S. Investor even if we are not a PFIC for such years. A U.S. Investor is encouraged to consult its tax advisor with respect to any available elections that may be applicable in such a situation, including the "deemed sale" election of Section 1298(b)(1) of the Code. In addition, U.S. Investors should consult their tax advisors regarding the IRS information reporting and filing obligations that may arise as a result of the ownership of shares in a PFIC, including IRS Form 8621.

We may invest in the equity of foreign corporations that are PFICs or may own subsidiaries that own PFICs. U.S. Investors will be subject to the PFIC rules with respect to their indirect ownership interests in such PFICs, such that a disposition of the shares of the PFIC or receipt by us of a distribution from the PFIC generally will be treated as a deemed disposition of such shares or the deemed receipt of such distribution by the U.S. Investor, subject to taxation under the PFIC rules. There can be no assurance that a U.S. Investor will be able to make a QEF election or a mark-to-market election with respect to PFICs in which we invest. Each U.S. Investor is encouraged to consult its own tax advisor with respect to tax consequences of an investment by us in a corporation that is a PFIC.

The U.S. federal income tax rules relating to PFICs are complex. U.S. Investors are urged to consult their own tax advisors with respect to the purchase, ownership and disposition of ordinary shares or ADSs, any elections available with respect to such ordinary shares or ADSs and the IRS information reporting obligations with respect to the purchase, ownership and disposition of ordinary shares or ADSs.

Certain Reporting Requirements

Certain U.S. Investors may be required to file IRS Form 926, Return by U.S. Transferor of Property to a Foreign Corporation and IRS Form 5471, Information Return of U.S. Persons With Respect to Certain Foreign Corporations, reporting transfers of cash or other property to us and information relating to the U.S. Investor and us. Substantial penalties may be imposed upon a U.S. Investor that fails to comply.

Certain U.S. Investors owning "specified foreign financial assets" with an aggregate value in excess of $50,000 on the last day of the taxable year or $75,000 at any time during the taxable year (or such higher dollar amount as may be prescribed by applicable IRS guidance) may be required to file IRS Form 8938, Statement of Specified Foreign Financial Assets, with respect to such assets with their tax returns. "Specified foreign financial assets" generally include any financial accounts maintained by foreign financial institutions, as well as any of the following held for investment and not held in accounts maintained by financial institutions: (i) stocks and securities issued by non-U.S. persons, which may include the ordinary shares or ADSs, (ii) financial instruments and contracts held for investment that have non-U.S. issuers or counterparties and (iii) interests in foreign entities. The IRS has issued guidance exempting "specified foreign financial assets" held in a financial account from reporting under this provision (although the financial account itself, if maintained by a foreign financial institution, may remain subject to this reporting requirement). U.S. Investors are urged to consult their tax advisors regarding the application of these requirements to their ownership of the ordinary shares or ADSs.

If we are treated as a PFIC, U.S. Investors may be required to file annual tax returns (including on IRS Form 8621) containing such information as the U.S. Treasury requires. A U.S. Investor that is not otherwise required to file a U.S. tax return must still file IRS Form 8621 in accordance with the instructions for the Form.

Backup Withholding Tax and Information Reporting Requirements

Generally, information reporting requirements will apply to distributions on our ordinary shares or ADSs or proceeds on the disposition of our ordinary shares or ADSs paid within the United States (and, in certain cases, outside the United States) to U.S. Investors other than certain exempt recipients, such as corporations. Furthermore, backup withholding may apply to such amounts if the U.S. Investor fails to (i) provide a correct taxpayer identification number, (ii) report interest and dividends required to be shown on its U.S. federal income tax return, or (iii) make other appropriate certifications in the required manner. U.S. Investors who are required to establish their exempt status generally must provide such certification on IRS Form W-9.

Backup withholding is not an additional tax. Amounts withheld as backup withholding from a payment may be credited against a U.S. Investor's U.S. federal income tax liability and such U.S. Investor may obtain a refund of any excess amounts withheld by timely filing the appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

U.S. Investors should consult their own tax advisors concerning the tax consequences relating to the purchase, ownership and disposition of the ordinary shares or ADSs.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are currently subject to the information and periodic reporting requirements of the Exchange Act, and file periodic reports and other information with the SEC through its electronic data gathering, analysis and retrieval (EDGAR) system. As a foreign private issuer, all documents which were filed after September 24, 2010 on the SEC's EDGAR system are available for retrieval on the SEC's website at www.sec.gov.

As a foreign private issuer, we are exempt from the rules 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 United States companies whose securities are registered under the Exchange Act.

In addition, since our ordinary shares are traded on the TASE, we also file periodic and immediate reports with, and furnish information to, the TASE and the ISA, or the ISA, as required under Chapter Six of the Israel Securities Law, 1968 and the regulations enacted pursuant thereof, as applicable to a public company which also trades on Nasdaq. Copies of our filings with the ISA can be retrieved electronically through the MAGNA distribution site of the ISA (*www.magna.isa.gov.il*) and the TASE website (*www.maya.tase.co.il*).

We maintain a corporate website at *www.biolinerx.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. We have included our website address in this Annual Report on Form 20-F solely as an inactive textual reference.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURE ON 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 consolidated financial position, results of operations or cash flows. We do not use derivative financial instruments for trading purposes. Accordingly, we have concluded that there is no material market risk exposure of the type contemplated by Item 11, and that no quantitative tabular disclosures are required. We are exposed to certain other types of market risks, as described below.

Risk of Interest Rate Fluctuation

Our investments consist primarily of cash, cash equivalents and short-term bank deposits. We may also invest in investment-grade marketable securities with maturities of up to three years, including commercial paper, money market funds, and government/non-government debt securities. The primary objective of our investment activities is to preserve principal while maximizing the income that we receive from our investments without significantly increasing risk and loss. Our investments are exposed to market risk due to fluctuation 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. Due to the short-term maturities of our investments to date, their carrying value has always approximated their fair value. It will be our policy to hold investments to maturity in order to limit our exposure to interest rate fluctuations.

Foreign Currency Exchange Risk

Our reporting and functional currency is the dollar. However, we pay a significant portion of our expenses in NIS and in euro, and we expect this to continue. If the dollar weakens against the NIS or the euro in the future, there may be a negative impact on our results of operations. The revenues from our current out-licensing and co-development arrangements are payable in dollars and euros. Although we expect our revenues from future licensing arrangements to be denominated primarily in dollars, we are exposed to the currency fluctuation risks relating to the recording of our revenues in currencies other than dollars. For example, if the euro strengthens against the dollar, our reported revenues in dollars may be lower than anticipated. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition for the periods under review.

From time to time, we have engaged in currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies, and we may continue to do so in the future. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

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

Set forth below is a summary of some of the material terms of the deposit agreement among BioLineRx, The Bank of New York Mellon as depositary, or the Depositary, and the owners and holders from time to time of our ADSs.

Description of the ADSs

Each of our ADSs represents 15 of our ordinary shares deposited with the principal Tel Aviv office of either Bank Hapoalim B.M. or Bank Leumi Le-Israel, as Custodian for the Depositary. Our ADSs trade on Nasdaq.

The form of the deposit agreement for the ADS 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.

Charges of Depositary

We will pay the fees, reasonable expenses and out-of-pocket charges of the Depositary and those of any registrar only in accordance with agreements in writing entered into between us and the Depositary from time to time. The following charges shall be incurred by any party depositing or withdrawing ordinary shares or by any party surrendering ADRs or to whom ADRs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADRs or deposited ordinary shares or a distribution of ADRs pursuant to the terms of the deposit agreement):

- taxes and other governmental charges;
- any applicable transfer or registration fees;
- certain cable, telex and facsimile transmission charges as provided in the deposit agreement;
- any expenses incurred in the conversion of foreign currency;
- a fee of $5.00 or less per 100 ADSs (or a portion thereof) for the execution and delivery of ADRs and the surrender of ADRs, including if the deposit agreement terminates;

- a fee of $.05 or less per ADS (or portion thereof) for any cash distribution made pursuant to the deposit agreement;
- a fee for the distribution of securities pursuant to the deposit agreement;
- in addition to any fee charged for a cash distribution, a fee of $.05 or less per ADS (or portion thereof) per annum for depositary services;
- a fee for the distribution of proceeds of rights that the Depositary sells pursuant to the deposit agreement; and
- any other charges payable by the Depositary, any of the Depositary's agents, or the agents of the Depositary's agents in connection with the servicing of ordinary shares or other Deposited Securities.

The Depositary may own and deal in our securities and in ADSs.

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 dealers or other service providers that are owned by or affiliated with the Depositary and that may earn or share fees, spreads or commissions.

The Depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the Depositary or its affiliate receives when buying or selling foreign currency for its own account. The Depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the Depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Liability of Holders for Taxes, Duties or Other Charges

Any tax or other governmental charge with respect to ADSs or any deposited ordinary shares represented by any ADS shall be payable by the holder of such ADS to the Depositary. The Depositary may refuse to effect transfer of such ADS or any withdrawal of deposited ordinary shares represented by such ADS until such payment is made, and may withhold any dividends or other distributions or may sell for the account of the holder any part or all of the deposited ordinary shares represented by such ADS and may apply such dividends or distributions or the proceeds of any such sale in payment of any such tax or other governmental charge and the holder of such ADS shall remain liable for any deficiency.

ITEM 13. DEFAULTS, DIVIDENDS 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, or the CEO, and the Chief Financial Officer, or the CFO, has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this report are effective. Notwithstanding the foregoing, there can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within the Company to disclose material information otherwise required to be set forth in our reports.

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 to our management and board of directors 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 CEO and CFO, 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 our internal control over financial reporting was effective as of December 31, 2021.

c. **Attestation Report of Registered Public Accounting Firm**

Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Ltd., our independent registered public accounting firm, has issued an attestation report on the effectiveness of our internal control over financial reporting, appearing under "Item 18. Financial Statements" on page F-2, and such report is incorporated herein by reference.

d. **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2021 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 EXPERTS

Our Board of Directors has determined that Ms. Nurit Benjamini is the audit committee financial expert. Ms. Benjamini is one of our independent directors for the purposes of the Nasdaq Rules.

ITEM 16B. CODE OF ETHICS

In July 2011, our Board of Directors adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that applies to all our employees, including without limitation our CEO, CFO and controller. Our Code of Conduct may be viewed on our website at *www.biolinerx.com*. A copy of our Code of Conduct may be obtained, without charge, upon a written request addressed to our investor relations department, 2 HaMa'ayan Street, Modi'in 7177871, Israel (Telephone no. +972-8-642-9100) (e-mail: info@BioLineRx.com).

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

The following table sets forth, for each of the years indicated, the fees billed by Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Ltd., our independent registered public accounting firm.

	Year Ended December 31,	
	2020	**2021**
Services Rendered	*(in thousands of U.S. dollars)*	
Audit Fees[1]	110	130
Audit-Related Fees[2]	38	25
Tax Fees[3]	16	20
All Other Fees	-	-
Total	164	175

(1) Audit fees consist of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide.

(2) Audit-related services relate to reports to the IIA and work regarding a public listing or offering.

(3) Tax fees relate to tax compliance, planning and advice.

Our Audit Committee, in accordance with its charter, reviews and pre-approves all audit services and permitted non-audit services (including the fees and other terms) to be provided by our independent auditors.

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

Nasdaq Listing Rules and Home Country Practices

The Sarbanes-Oxley Act, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, such as us, to comply with various corporate governance practices. In complying with the Nasdaq Rules, we have elected to follow certain corporate governance practices permitted under the Companies Law and the rules of the TASE in lieu of compliance with certain corporate governance requirements otherwise required by the Nasdaq Rules.

In accordance with Israeli law and practice and subject to the exemption set forth in Rule 5615 of the Nasdaq Rules, we follow the provisions of the Companies Law, rather than the Nasdaq Rules, with respect to the following requirements:

- *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 ISA and the TASE. In addition, we make our audited financial statements available to our shareholders at our offices. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.

- Quorum. While the Nasdaq Rules require that the quorum for purposes of any meeting of the holders of a listed company's common voting stock, as specified in the company's bylaws, be no less than 33 1/3% of the company's outstanding common voting stock, under Israeli law, a company is entitled to determine in its articles of association the number of shareholders and percentage of holdings required for a quorum at a shareholders meeting. Our Articles of Association provide that a quorum of two or more shareholders holding at least 25% of the voting rights in person or by proxy is required for commencement of business at a general meeting. However, the quorum set forth in our Articles of Association with respect to an adjourned meeting consists of any number of shareholders present in person or by proxy.

- Independent Directors. Our Board of Directors includes two external directors in accordance with the provisions contained in Sections 239-249 of the Companies Law and Rule 10A-3 of the general rules and regulations promulgated under the Securities Act, rather than a majority of independent directors. Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only they are present. We are required, however, to ensure that all members of our Audit Committee are "independent" under the applicable Nasdaq and SEC criteria for independence (as a foreign private issuer we are not exempt from the SEC independence requirement), and we must also ensure that a majority of the members of our Audit Committee are independent directors as defined in the Companies Law. Furthermore, Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only they are present, which the Nasdaq Rules otherwise require. If we qualify as an Eligible Company and opt to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees, we will be required at all times to comply with the U.S. rules and regulations governing the appointment of independent directors and composition of the audit and compensation committees applicable to U.S. domestic issuers instead of complying with the Companies Law provisions relating to external directors and composition of the audit and compensation committees.

- Audit Committee. Our Audit Committee complies with all of the requirements under Israeli law, and is composed of two external directors, which are all of our external directors, and only one other director, who cannot be the chairman of our Board of Directors. Consistent with Israeli law, the independent auditors are elected at a meeting of shareholders instead of being appointed by the Audit Committee. If we qualify as an Eligible Company and opt to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees, we will be required at all times to comply with the U.S. rules and regulations governing the appointment of independent directors and composition of the Audit Committee applicable to U.S. domestic issuers instead of complying with the Companies Law provisions relating to external directors and composition of the Audit Committee.

- Nomination of our Directors. With the exception of our external directors and directors elected by our Board of Directors due to vacancy, our directors are elected by a general or extraordinary meeting of our shareholders, to hold office until they are removed from office by the majority of our shareholders at a general or extraordinary meeting of our shareholders. See "Item 6. Directors, Senior Management and Employees — Board Practices — Board of Directors." 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 under the Companies Law or in an agreement between us and our shareholders. Currently, there is no agreement between us and any shareholder regarding the nomination of directors. In accordance with our Articles of Association, under the Companies Law, any one or more shareholders holding, in the aggregate, either (1) at least 5% of our outstanding shares and at least 1% of our outstanding voting power or (2) at least 5% of our outstanding voting power, may nominate one or more persons for election as directors at a general or special meeting by delivering a written notice of such shareholder's intent to make such nomination or nominations to our registered office. Each such notice must set forth all of the details and information as required to be provided in the Companies Law.

- Compensation Committee and Compensation of Officers. Israeli law, and our Articles of Association, do not require that a compensation committee composed solely of independent members of our Board of Directors determine (or recommend to the board of directors for determination) an executive officer's compensation, as required under Nasdaq's listing standards related to compensation committee independence and responsibilities; nor do they require that the Company adopt and file a compensation committee charter. Instead, our Compensation Committee has been established and conducts itself in accordance with provisions governing the composition of and the responsibilities of a compensation committee as set forth in the Companies Law, and is comprised of all of our external directors (who must comprise the majority of the members of the Compensation Committee), and at least one additional director who is entitled to the same compensation payable to our external directors, and who is not the chairman of our Board of Directors or otherwise employed by or a provider of services to, the Company. If we qualify as an Eligible Company and opt to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees, we will be required at all times to comply with the U.S. rules and regulations governing the appointment of independent directors and composition of the compensation committee applicable to U.S. domestic issuers instead of complying with the Companies Law provisions relating to external directors and composition of the compensation committee. Additionally, we comply with the requirements set forth under the Companies Law, pursuant to which transactions with office holders regarding their terms of office and employment, and a transaction with a controlling shareholder in a company regarding his or her employment and/or his or her terms of office with the company, may require the approval of the compensation committee, the board of directors and under certain circumstances the shareholders, either in accordance with our previously approved compensation policy or, in special circumstances in deviation therefrom, taking into account certain considerations set forth in the Companies Law. See "Item 6. Directors, Senior Management and Employees — Board Practices — Compensation Committee" for information regarding the Compensation Committee, and "Item 6. Directors, Senior Management and Employees — Approval of Related Party Transactions under Israeli Law" for information regarding the special approvals required with respect to approval of terms of office and employment of office holders, pursuant to the Companies Law. The requirements for shareholder approval of any office holder compensation, and the relevant majority or special majority for such approval, are all as set forth in the Companies Law. Thus, we will seek shareholder approval for all corporate actions with respect to office holder compensation requiring such approval under the requirements of the Companies Law, including seeking prior approval of the shareholders for the compensation policy and for certain office holder compensation, rather than seeking approval for such corporate actions in accordance with Nasdaq Listing Rules.

- Approval of Related Party Transactions. All related party transactions are approved in accordance with the requirements and procedures for approval of interested party acts and transactions, set forth in sections 268 to 275 of the Companies Law, and the regulations promulgated thereunder, which require the approval of the audit committee, the compensation committee, the board of directors and shareholders, as may be applicable, for specified transactions, rather than approval by the audit committee or other independent body of our Board of Directors as required under the Nasdaq Rules.

- 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 or in addition to the requirements for seeking shareholder approval under Nasdaq Listing Rule 5635, rather than seeking approval for corporation actions in accordance with such listing rules.

- Equity Compensation Plans. We do not necessarily seek shareholder approval for the establishment of, and amendments to, stock option or equity compensation plans (as set forth in Nasdaq Listing Rule 5635(c)), as such matters are not subject to shareholder approval under Israeli law. Our equity compensation plan is available to our employees, none of whom are currently U.S. employees, and provides features necessary to comply with applicable non-U.S. tax laws.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 17. FINANCIAL STATEMENTS

The Registrant has responded to Item 18 in lieu of responding to this Item.

ITEM 18. FINANCIAL STATEMENTS

See the financial statements beginning on page F-1. The following financial statements are filed as part of this Annual Report on Form 20-F together with the report of the independent registered public accounting firm.

ITEM 19. EXHIBITS

Exhibit Number	Exhibit Description
2.1(1)	Articles of Association, as amended September 24, 2020
2.2(1)	Description of Securities Registered under Section 12
2.3(2)	Deposit Agreement dated as of July 21, 2011 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 thereunder
2.4(2)	Form of American Depositary Receipt; the Form is Exhibit A of the deposit agreement which is Exhibit 2.2 above.
4.1(3)	Employment Agreement with Philip Serlin, dated May 24, 2009
4.2(1)	Amendment to Employment Agreement between BioLineRx Ltd. and Philip Serlin, dated September 24, 2020
4.3(3)	Employment Agreement with Mali Zeevi, dated September 16, 2009
4.4(1)	Amendment to Employment Agreement between BioLineRx Ltd and Mali Zeevi, dated September 24, 2020
4.5(3)	Employment Agreement with Abi Vainstein-Hara, dated April 2, 2014
4.6(1)	Amendment to Employment Agreement between BioLineRx Ltd and Abi Vainstein-Hara, dated September 24, 2020
4.7(2)	Employment Agreement with Ella Sorani, dated January 11, 2017
4.8(1)	Amendment to Employment Agreement between BioLineRx Ltd and Ella Sorani, dated September 24, 2020
4.9†(4)	License Agreement entered into as of November 25, 2007 between BioLine Innovations Jerusalem L.P. and Innovative Pharmaceutical Concepts, Inc.
4.10(5)	BioLineRx Ltd. Amended and Restated 2003 Share Incentive Plan
4.11(6)	License Agreement entered into as of September 2, 2012 by and between the Registrant and Biokine Therapeutics Ltd.
4.12(7)†	Amendment Agreement entered into as of October 2, 2018 by and between the Registrant and Biokine Therapeutics Ltd.
4.13(7)	Loan Agreement entered into as of October 2, 2018, by and between the Registrant and Kreos Capital V (Expert Fund) L.P.

4.14(7)	Warrant issued to Kreos Capital V dated October 2, 2018
4.15(8)	Compensation Policy for Executives and Directors, as amended
4.16	Amendment to the Compensation Policy for Executives and Directors
4.17(9)	Lease Agreement entered into as of August 7, 2014 between S.M.L. Solomon Industrial Buildings Ltd. and Infrastructure Management and Development Established by C.P.M. Ltd. as Lessor and the Registrant as Lessee, as amended (English summary of the Hebrew original)
4.18(10)†	License Agreement entered into as of December 22, 2014 between the Registrant and Wartner Europe BV
4.19†	Clinical Trial Collaboration and Supply Agreement entered into as of January 11, 2016 between the Registrant and Merck Sharp & Dohme B.V.
4.20†	Amendment No. 2 to Clinical Trial Collaboration and Supply Agreement entered into as of July 24, 2018 between the Registrant and Merck Sharp & Dohme B.V.
4.21(3)†	Amended and Restated Exclusive License Agreement entered into as of April 30, 2013 between the University of Massachusetts and Agalimmune Ltd.
4.22†	Patent and Know-how License Agreement entered into as of September 19, 2017 between Kode Biotech Limited and Agalimmune Ltd.
4.23†	Second Amendment Agreement entered into as of October 16, 2018 between the University of Massachusetts and Agalimmune Ltd.
4.24†	Amendment No. 1 to License Agreement entered into as of June 18, 2018 between the Registrant and Wartner Europe BV
4.25(8)	First Addendum to License Agreement entered into as of October 16, 2019 by and between the Registrant and Biokine Therapeutics Ltd., as amended.
4.26(11)	Form of Warrant issued February 7, 2019
4.27 (12)	Form of Warrant issued by BioLineRx Ltd. on May 28, 2020
4.28(12)	Form of Placement Agent Warrant issued by BioLineRx Ltd. on May 28, 2020
4.29(13)	Form of Warrant issued by BioLineRx Ltd. on June 3, 2020
4.30(13)	Form of Placement Agent Warrant issued by BioLineRx Ltd. on June 3, 2020
4.31(14)	Amended and Restated Underwriting Agreement, dated January 19, 2021, by and between BioLineRx Ltd. and H.C. Wainwright & Co., LLC
4.32(14)	Form of Underwriter Warrant to be issued by BioLineRx Ltd. on January 22, 2021
4.33(15)	At-the-Market Sales Agreement, dated September 3, 2021, between BioLineRx Ltd. and H.C. Wainwright & Co., LLC
8.1	List of Subsidiaries of BioLineRx Ltd.
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 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant
101	The following financial information from BioLineRx Ltd.'s Annual Report on Form 20-F for the fiscal year ended December 31, 2021 formatted in Inline XBRL (Extensible Business Reporting Language): (i) Consolidated Statements of Financial Position at December 31, 2021 and 2020; (ii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2021, 2020 and 2019; (iii) Statements of Changes in Equity for the years ended December 31, 2021, 2020 and 2019; (iv) Consolidated Cash Flow Statements for the years ended December 31, 2021, 2020 and 2019; and (v) Notes to the Consolidated Financial Statements.

Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

(1) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on February 23, 2021.

(2) Incorporated by reference to Exhibit 1 of the Registration Statement on Form F-6EF (No. 333-218969) filed by the Bank of New York Mellon on June 26, 2017 with respect to the Registrant's American Depositary Shares.

(3) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 23, 2017.

(4) Incorporated by reference to the Registrant's Registration Statement on Form 20-F (No. 001-35223) filed on July 1, 2011.

(5) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 10, 2016.

(6) Incorporated by reference to the Registrant's Annual Report on Form 20-F/A filed on May 31, 2016.

(7) Incorporated by reference to the Registrant's Form 6-K filed on October 3, 2018.

(8) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 12, 2020.

(9) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 23, 2015.

(10) Incorporated by reference to the Registrant's Annual Report on Form 20-F/A filed on September 22, 2015.

(11) Incorporated by reference to the Registrant's Form 6-K filed on February 7, 2019.

(12) Incorporated by reference to the Registrant's Form 6-K filed on May 28, 2020.

(13) Incorporated by reference to the Registrant's Form 6-K filed on June 3, 2020.

(14) Incorporated by reference to the Registrant's Form 6-K filed on January 22, 2021.

(15) Incorporated by reference to the Registrant's Form 6-K filed on September 3, 2021.

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

BIOLINERX LTD.

By: /s/ Philip A. Serlin
Philip A. Serlin
Chief Executive Officer

Date: March 16, 2022

BioLineRx Ltd.
INDEX TO FINANCIAL STATEMENTS:

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of BioLineRx Ltd.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated statements of financial position of BioLineRx Ltd. and its subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2021, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 15(b). Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

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 (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Intellectual Property Impairment Assessment

As described in Notes 4 and 8 to the consolidated financial statements, the Company's intangible assets relating to intellectual property balance was $21.7 million as of December 31, 2021. Management conducts an impairment test as of December 31 of each year, or more frequently if events or circumstances indicate that the carrying value of the intellectual property may be impaired. Potential impairment is identified by comparing the fair value of the intellectual property to its carrying value. Fair value is estimated by management using a discounted cash flow model. Management's cash flow projections included significant judgments and assumptions relating to weighted average cost of capital and the amount and timing of projected future cash flows.

The principal considerations for our determination that performing procedures relating to the intellectual property impairment assessment is a critical audit matter are the significant judgment by management in developing the weighted average cost of capital and the amount and timing of projected future cash flows. This in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures to evaluate these assumptions. In addition, the audit effort involved the use of professionals with specialized skill and knowledge to assist in performing these procedures and evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's intangible asset impairment assessment, including controls over the determination of the cash flow projections and the significant assumptions used. These procedures also included, among others, testing management's process for developing the fair value estimate; evaluating the appropriateness of the discounted cash flow model; testing the completeness, accuracy, and relevance of underlying data used in the model; and evaluating the significant assumptions used by management, including the weighted average cost of capital and the amount and timing of projected future cash flows. Evaluating management's assumptions related to the weighted average cost of capital and the amount and timing of projected future cash flows involved evaluating whether the assumptions used by management were reasonable considering the consistency with external market and industry data. Professionals with specialized skill and knowledge were used to assist in the evaluation of management's valuation model and certain significant assumptions.

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Ltd.

Tel Aviv, Israel
March 15, 2022

We have served as the Company's auditor since 2003.

BioLineRx Ltd.
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31,	
		2020	2021
		in USD thousands	
Assets			
CURRENT ASSETS			
Cash and cash equivalents	5	16,831	12,990
Short-term bank deposits	6	5,756	44,145
Prepaid expenses		152	127
Other receivables	16a	141	142
Total current assets		22,880	57,404
NON-CURRENT ASSETS			
Property and equipment, net	7	1,341	952
Right-of-use assets, net	9	1,355	1,331
Intangible assets, net	8	21,714	21,704
Total non-current assets		24,410	23,987
Total assets		47,290	81,391
Liabilities and equity			
CURRENT LIABILITIES			
Current maturities of long-term loan	10	3,092	2,757
Accounts payable and accruals:			
Trade	16b	5,918	5,567
Other	16b	1,440	1,227
Current maturities of lease liabilities	9	191	168
Total current liabilities		10,641	9,719
NON-CURRENT LIABILITIES			
Warrants	11c	10,218	1,859
Long-term loan, net of current maturities	10	2,740	-
Lease liabilities	9	1,661	1,726
Total non-current liabilities		14,619	3,585
COMMITMENTS AND CONTINGENT LIABILITIES	14		
Total liabilities		25,260	13,304
EQUITY	11		
Ordinary shares		9,870	21,066
Share premium		279,241	339,346
Warrants		-	975
Capital reserve		12,322	13,157
Other comprehensive loss		(1,416)	(1,416)
Accumulated deficit		(277,987)	(305,041)
Total equity		22,030	68,087
Total liabilities and equity		47,290	81,391

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

BioLineRx Ltd.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year ended December 31,		
		2019	2020	2021
		in USD thousands		
RESEARCH AND DEVELOPMENT EXPENSES	16c	(23,438)	(18,173)	(19,466)
SALES AND MARKETING EXPENSES	16d	(857)	(840)	(1,003)
GENERAL AND ADMINISTRATIVE EXPENSES	16e	(3,816)	(3,914)	(4,308)
OPERATING LOSS		(28,111)	(22,927)	(24,777)
NON-OPERATING INCOME (EXPENSES), NET	16f	4,165	(5,701)	(1,830)
FINANCIAL INCOME	16g	777	236	559
FINANCIAL EXPENSES	16h	(2,277)	(1,629)	(1,006)
LOSS AND COMPREHENSIVE LOSS		(25,446)	(30,021)	(27,054)
		in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	13	(0.17)	(0.12)	(0.04)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	13	146,407,055	252,844,394	662,933,695

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

BioLineRx Ltd.
STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Share premium	Warrants	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
				in USD thousands			
BALANCE AT JANUARY 1, 2019	3,110	250,192	-	11,955	(1,416)	(222,520)	41,321
CHANGES IN 2019:							
Issuance of share capital and warrants, net	1,580	14,165	-	-	-	-	15,745
Employee stock options exercised	2	83	-	(84)	-	-	1
Employee stock options forfeited and expired	-	1,498	-	(1,498)	-	-	-
Share-based compensation	-	-	-	1,759	-	-	1,759
Comprehensive loss for the year	-	-	-	-	-	(25,446)	(25,446)
BALANCE AT DECEMBER 31, 2019	4,692	265,938	-	12,132	(1,416)	(247,966)	33,380
CHANGES IN 2020:							
Issuance of share capital and warrants, net	4,777	9,395	-	-	-	-	14,172
Warrants exercised	393	2,826	-	-	-	-	3,219
Employee stock options exercised	8	228	-	(228)	-	-	8
Employee stock options forfeited and expired	-	854	-	(854)	-	-	-
Share-based compensation	-	-	-	1,272	-	-	1,272
Comprehensive loss for the year	-	-	-	-	-	(30,021)	(30,021)
BALANCE AT DECEMBER 31, 2020	9,870	279,241	-	12,322	(1,416)	(277,987)	22,030
CHANGES IN 2021:							
Issuance of share capital and warrants, net	8,956	40,476	975	-	-	-	50,407
Warrants exercised	2,235	18,967	-	-	-	-	21,202
Employee stock options exercised	5	41	-	(39)	-	-	7
Employee stock options forfeited and expired	-	621	-	(621)	-	-	-
Share-based compensation	-	-	-	1,495	-	-	1,495
Comprehensive loss for the year	-	-	-	-	-	(27,054)	(27,054)
BALANCE AT DECEMBER 31, 2021	21,066	339,346	975	13,157	(1,416)	(305,041)	68,087

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

BioLineRx Ltd.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2019	2020	2021
	in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES			
Loss	(25,446)	(30,021)	(27,054)
Adjustments required to reflect net cash used in operating activities (see appendix below)	2,780	6,815	3,481
Net cash used in operating activities	(22,666)	(23,206)	(23,573)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(43,545)	(33,500)	(78,000)
Maturities of short-term deposits	48,875	50,168	39,873
Purchase of property and equipment	(67)	-	(97)
Purchase of intangible assets	(6)	-	-
Net cash provided by (used in) investing activities	5,257	16,668	(38,224)
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance costs	20,297	19,246	50,407
Exercise of warrants	-	1,969	10,907
Employee stock options exercised	1	8	7
Repayments of loans	(889)	(3,133)	(3,376)
Repayments of lease liabilities	(215)	(224)	(196)
Net cash provided by financing activities	19,194	17,866	57,749
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,785	11,328	(4,048)
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	3,404	5,297	16,831
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	108	206	207
CASH AND CASH EQUIVALENTS - END OF YEAR	5,297	16,831	12,990

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

BioLineRx Ltd.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2019	2020	2021
		in USD thousands	
APPENDIX			
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	940	934	703
Long-term prepaid expenses	56	-	-
Exchange differences on cash and cash equivalents	(108)	(206)	(207)
Fair value adjustments of warrants	(4,634)	5,142	1,936
Share-based compensation	1,759	1,272	1,495
Interest on short-term deposits	(775)	(232)	(262)
Interest on loans	647	474	301
Warrant issuance costs	417	594	-
Exchange differences on lease liabilities	154	125	55
	(1,544)	8,103	4,021
Changes in operating asset and liability items:			
Decrease in prepaid expenses and other receivables	1,106	428	24
Increase (decrease) in accounts payable and accruals	3,218	(1,716)	(564)
	4,324	(1,288)	(540)
	2,780	6,815	3,481
Supplemental information on interest received in cash	868	381	138
Supplemental information on interest paid in cash (see Notes 9 and 10)	1,198	994	682
Supplemental information on non-cash transactions (see Notes 9 and 11c)	147	1,251	10,112

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

NOTE 1 – GENERAL INFORMATION

a. General

BioLineRx Ltd. ("BioLineRx"), headquartered in Modi'in, Israel, was incorporated and commenced operations in April 2003.

BioLineRx and its subsidiaries (collectively, the "Company") are engaged in the development of therapeutics, primarily in clinical stages, with a focus on the field of oncology.

In 2017, the Company acquired substantially all the outstanding shares of Agalimmune Ltd. ("Agalimmune"), a private company incorporated in the United Kingdom, with a focus on the field of immuno-oncology.

In February 2007, BioLineRx listed its ordinary shares on the Tel Aviv Stock Exchange ("TASE") and they have been traded on the TASE since that time. Since July 2011, BioLineRx's American Depositary Shares ("ADSs") have also been traded on the NASDAQ Capital Market.

The Company has incurred accumulated losses in the amount of $305 million through December 31, 2021 and cannot determine with reasonable certainty when and if it will have sustainable profits. See Note 3c with regard to the Company's management of liquidity risk.

b. Approval of consolidated financial statements

The consolidated financial statements of the Company for the year ended December 31, 2021 were approved by the Board of Directors on March 15, 2022, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial Officer.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation

The Company's consolidated financial statements as of December 31, 2020 and 2021, and for each of the three years in the period ended December 31, 2021, have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). The significant accounting policies described below have been applied on a consistent basis for all years presented, unless noted otherwise.

The consolidated financial statements have been prepared on the basis of historical cost, subject to adjustment of warrant liabilities to their fair value through profit or loss.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

a. Basis of presentation (cont.)

The preparation of financial statements in conformity with IFRS requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity and expenses, as well as the related disclosures of contingent assets and liabilities, in the process of applying the Company's accounting policies. Actual results could differ from those estimates.

Areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed in Note 4. Actual results may differ materially from estimates and assumptions used by the Company's management.

b. Principles of consolidation

Consolidated entities are all entities over which BioLineRx has control. BioLineRx controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Consolidated entities are fully consolidated from the date on which control of such entities is transferred to BioLineRx and they are de-consolidated from the date that control ceases.

c. Functional and reporting currency

The functional and reporting currency in these financial statements is the U.S. dollar ("dollar", "USD" or "$"), which is the primary currency of the economic environment in which the Company operates. Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year-end exchange rates are generally recognized in profit or loss.

Foreign exchange gains and losses that relate to borrowings are presented in the statement of comprehensive loss, within financial expenses.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

d. Cash equivalents and short-term bank deposits

Cash and cash equivalents include cash on hand and short-term bank deposits (up to three months from date of deposit) that are not restricted as to withdrawal or use. Bank deposits with original maturity dates of more than three months and with a current maturity date of less than one year from the balance sheet date are included in short-term bank deposits. The fair value of cash equivalents and short-term bank deposits approximate their carrying value, since they bear interest at rates close to the prevailing market rates.

e. Property and equipment

Property and equipment are stated at historical cost less depreciation. Historical cost includes expenditures that are directly attributable to the acquisition of the items. Assets are depreciated by the straight-line method over the estimated useful lives of the assets, provided that the Company's management believes the residual values of the assets to be negligible, as follows:

	%
Computers and communications equipment	20-33
Office furniture and equipment	6-15
Laboratory equipment	15-20

The assets' residual values, methods of depreciation and useful lives are reviewed and adjusted, if appropriate, at each balance sheet date. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Leasehold improvements are amortized by the straight-line method over the shorter of the lease term or the estimated useful life of the improvements.

f. Intangible assets

The Company applies the cost method of accounting for initial and subsequent measurements of intangible assets. Under this method of accounting, intangible assets are carried at cost less any accumulated amortization and any accumulated impairment losses.

Intellectual property
The Company recognizes in its financial statements intangible assets developed by the Company to the extent that the conditions stipulated in o. below are met. Intellectual property acquired by the Company is initially measured at cost. Intellectual property acquired by the Company for development purposes is not amortized and is tested annually for impairment. See g. below.

Computer software
Acquired computer software licenses are capitalized on the basis of the costs incurred to acquire and bring to use the specific software. These costs are amortized over the estimated useful lives of the software (3-5 years).

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

g. Impairment of non-financial assets

Impairment of intellectual property is required when the Company decides to terminate or suspend the development of a project based on such intellectual property. In addition, the Company performs impairment reviews on an annual basis, or more frequently if events or changes in circumstances indicate a potential impairment. Property and equipment, as well as computer software, are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized equal to the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and the asset's value in use to the Company.

h. Financial assets

The Company accounts for financial assets in accordance with IFRS 9 "Financial Instruments."

1) Classification

The financial assets of the Company are classified as financial assets at amortized cost. The classification is done on the basis of the Company's business model for managing the financial assets and the contractual cash flow characteristics of the financial assets.

Financial assets at amortized cost

Financial assets at amortized cost are assets held pursuant to a business model whose objective is to hold assets in order to collect contractual cash flows and the contractual terms of the financial assets give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets at amortized cost are included in current assets, except for those with maturities greater than 12 months after the balance sheet date (in which case they are classified as non-current assets).

The Company's financial assets at amortized cost are included in other receivables and bank deposits in the consolidated statements of financial position.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

h. Financial assets (cont.)

2) Recognition and measurement

Regular purchases and sales of financial assets are recognized on the settlement date, which is the date on which the asset is delivered to the Company or delivered by the Company. Investments are initially recognized at fair value plus transaction costs, except for trade receivables, which are recognized initially at the amount of consideration that is unconditional unless they contain significant financing components.

Financial assets are derecognized when the rights to receive cash flows from the investments have expired or have been transferred and the Company has transferred substantially all risks and rewards of ownership. Financial assets at amortized cost are measured in subsequent periods at amortized cost using the effective interest method.

3) Impairment

The Company recognizes a loss allowance for expected credit losses on financial assets at amortized cost. At each reporting date, the Company assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. If the financial instrument is determined to have low credit risk at the reporting date, the Company assumes that the credit risk on a financial instrument has not increased significantly since initial recognition.

i. Warrants

Receipts in respect of warrants are classified as equity to the extent that they confer the right to purchase a fixed number of shares for a fixed exercise price. In the event that the exercise price or the numbers of shares to be issued are not deemed to be fixed, the warrants are classified as a non-current derivative financial liability. This liability is initially recognized at its fair value on the date the contract is entered into and subsequently accounted for at fair value at each reporting date. The fair value changes are charged to non-operating income and expense on the statement of comprehensive loss. Issuance costs allocable to warrants are also recorded as non-operating expense on the statement of comprehensive loss.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

j. Share capital

The Company's ordinary shares are classified as equity. Incremental costs directly attributable to the issuance of new shares are shown in equity as a deduction from the issuance proceeds.

k. Trade payables

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. These payables are classified as current liabilities if payment is due within one year or less. If not, they are presented as non-current liabilities. Trade payables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method.

l. Deferred taxes

Deferred taxes are recognized using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred income tax assets are recognized only to the extent that it is probable that future taxable income will be available against which the temporary differences can be utilized.

As the Company is currently engaged primarily in development activities and is not expected to generate taxable income in the foreseeable future, no deferred tax assets are included in the financial statements.

m. Borrowings

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method.

Borrowings are classified as current liabilities unless the Company has an unconditional right to defer settlement of the liability for at least 12 months after the reporting period.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

n. Revenue from contracts with customers

The Company accounts for revenue in accordance with IFRS 15, "Revenue from Contracts with Customers."

IFRS 15 introduces a five-step model for recognizing revenue from contracts with customers, as follows:

- identify the contract with a customer;
- identify the performance obligations in the contract;
- determine the transaction price;
- allocate the transaction price to the performance obligations in the contract; and
- recognize revenue when (or as) the entity satisfies a performance obligation.

During the years included in these financial statements, the Company did not generate revenues, other than immaterial amounts received from an out-licensing agreement signed in 2014 with Perrigo Company plc., which have been included in non-operating income.

o. Research and development expenses

Research expenses are charged to profit or loss as incurred.

An intangible asset arising from development (or from the development phase of an internal project) is recognized if all of the following conditions are fulfilled:

- technological feasibility exists for completing development of the intangible asset so that it will be available for use or sale.
- it is management's intention to complete development of the intangible asset for use or sale.
- the Company has the ability to use or sell the intangible asset.
- it is probable that the intangible asset will generate future economic benefits, including existence of a market for the output of the intangible asset or the intangible asset itself or, if the intangible asset is to be used internally, the usefulness of the intangible asset.
- adequate technical, financial and other resources are available to complete development of the intangible asset, as well as the use or sale thereof.
- the Company has the ability to reliably measure the expenditure attributable to the intangible asset during its development.

Other development costs that do not meet the foregoing conditions are charged to profit or loss as incurred. Development costs previously expensed are not recognized as an asset in subsequent periods. As of December 31, 2021, the Company has not yet capitalized development expenses.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

p. Employee benefits

1) Pension and severance pay obligations

Israeli labor laws and the Company's employment agreements require the Company to pay retirement benefits to employees terminated or leaving their employment in certain other circumstances. Most of the Company's employees are covered by a defined contribution plan under Section 14 of the Israel Severance Pay Law.

With respect to the remaining employees, the Company records a liability on its balance sheet for defined benefit plans that represents the present value of the defined benefit obligation as of each reporting date, net of the fair value of plan assets. The present value of the defined benefit liability is determined by discounting the anticipated future cash outflows, using interest rates that are denominated in the currency in which the benefits will be payable.

The amounts recorded as an employee benefit expense in respect of pension and severance pay obligations for the years 2019, 2020 and 2021 were $580,000, $668,000 and $744,000, respectively.

2) Vacation and recreation pay

Labor laws in Israel entitle every employee to vacation and recreation pay, both of which are computed annually. The entitlement with respect to each employee is based on the employee's length of service at the Company. The Company recognizes a liability and an expense in respect of vacation and recreation pay based on the individual entitlement of each employee.

3) Share-based payments

The Company operates an equity-settled, share-based compensation plan, under which it grants equity instruments (options, restricted stock units and performance stock units) of the Company as additional consideration for services from employees and service providers. The fair value of the employee services received in exchange for grant of the equity instruments is recognized as an expense. The total amount to be expensed is determined by reference to the fair value of the equity instruments granted:

- including any market performance conditions (for example, the Company's share price); and
- excluding the impact of any service and non-market performance vesting conditions (for example, profitability, sales growth targets and the employee remaining with the entity over a specified time period).

Non-market performance and service conditions are included in assumptions about the number of equity instruments that are expected to vest. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. Performance stock unit expenses are recognized only if it is probable that the performance condition will be achieved.

When the equity instruments are exercised, the Company issues new shares. The proceeds received, net of any directly attributable transaction costs, are credited to share capital (at par value) and share premium when the equity instruments are exercised.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

q. Loss per share

1) Basic

The basic loss per share is calculated by dividing the loss attributable to the holders of ordinary shares by the weighted average number of ordinary shares outstanding during the year.

2) Diluted

The diluted loss per share is calculated by adjusting the weighted average number of outstanding ordinary shares, assuming conversion of all dilutive potential shares. The Company's dilutive potential shares consist of warrants issued to investors, as well as equity instruments granted to employees and service providers. The dilutive potential shares were not taken into account in computing loss per share in 2019, 2020 and 2021, as their effect would have been anti-dilutive.

r. Leases

The Company's leases include property and motor vehicle leases. At inception of a contract, the Company assesses whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company reassesses whether a contract is, or contains, a lease only if the terms and conditions of the contract are changed.

At the commencement date, the Company measures the lease liability at the present value of the lease payments that are not paid at that date, including, inter alia, the exercise price of a purchase option if the Company is reasonably certain to exercise that option. Simultaneously, the Company recognizes a right-of-use asset in the amount of the lease liability.

Since the interest rate implicit in the lease cannot be readily determined, the Company uses the Company's incremental borrowing rate. This rate is the rate of interest that the Company would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment.

The lease term is the non-cancellable period for which the Company has the right to use an underlying asset, together with both the periods covered by an option to extend the lease, if the Company is reasonably certain to exercise that option, and periods covered by an option to terminate the lease, if the Company is reasonably certain not to exercise that option.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

r. Leases (cont.)

After the commencement date, the Company measures the right-of-use asset applying the cost model, less any accumulated depreciation and any accumulated impairment losses and adjusted for any remeasurement of the lease liability

Assets are depreciated by the straight-line method over the estimated useful lives of the right of use assets or the lease period, which is shorter:

	Years
Property	11
Motor vehicles	3

Interest on the lease liability is recognized in profit or loss in each period during the lease term, in an amount that produces a constant periodic rate of interest on the remaining balance of the lease liability.

s. New standards and interpretations not yet adopted

Classification of Liabilities as Current or Non-current (Amendment to IAS 1)

The narrow-scope amendments to IAS 1, "Presentation of Financial Statements," clarify that liabilities are classified as either current or non-current, depending on the rights that exist at the end of the reporting period. Classification is unaffected by the expectations of the entity or events after the reporting date (e.g., the receipt of a waiver or a breach of covenant). The amendments also clarify what IAS 1 means when it refers to the "settlement" of a liability. The amendments could affect the classification of liabilities, particularly for entities that previously considered management's intentions to determine classification and for some liabilities that can be converted into equity. They must be applied retrospectively in accordance with the normal requirements in IAS 8, "Accounting Policies, Changes in Accounting Estimates and Errors." The amendment should be applied retrospectively for annual periods beginning on or after January 1, 2023. Earlier application is permitted. The adoption of the amendment is not expected to have a material impact on the Company's financial statements.

NOTE 3 – FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT

Based on assessments by Company management, the Company's exposure to credit risk as of December 31, 2021, is immaterial (see Note 3b). The activities of the Company expose it to market risk, primarily as a result of currency risk.

The Company's Finance Department is responsible for carrying out risk management activities in accordance with policies approved by its Board of Directors. In this regard, the Finance Department identifies, defines and assesses financial risks in close cooperation with other Company departments. The Board of Directors provides written guidelines for overall risk management, as well as written policies dealing with specific areas, such as exchange rate risk, interest rate risk, credit risk, use of financial instruments and investment of excess cash.

a. Market risk

1) Concentration of currency risk

The Company's activities are partly denominated in non-dollar currencies (primarily the New Israeli Shekel, or "NIS," and the Euro), which exposes the Company to risks resulting from changes in exchange rates.

The effect of fluctuations in various exchange rates on the Company's income and equity is as follows:

	December 31, 2021				
	Income (loss)		Value on	Income (loss)	
Sensitive instrument	10% increase	5% increase	balance sheet	5% decrease	10% decrease
			in USD thousands		
NIS-linked balances:					
Cash and cash equivalents	(427)	(224)	4,699	522	247
Other receivables	(13)	(7)	142	16	7
Trade payables	40	21	(442)	(49)	(23)
Other payables	102	53	(1,119)	(124)	(59)
Total NIS-linked balances	(298)	(157)	3,280	365	172
Euro-linked trade payables	(158)	(83)	(1,230)	193	92
Total	(456)	(240)	2,050	558	264

	December 31, 2020				
	Income (loss)		Value on	Income (loss)	
Sensitive instrument	10% increase	5% increase	balance sheet	5% decrease	10% decrease
			in USD thousands		
NIS-linked balances:					
Cash and cash equivalents	(341)	(179)	3,755	198	417
Other receivables	(13)	(7)	141	7	16
Trade payables	47	25	(518)	(27)	(58)
Other payables	117	61	(1,286)	(68)	(143)
Total NIS-linked balances	(190)	(100)	2,092	110	232
Euro-linked trade payables	(203)	(106)	(2,232)	248	117
Total	(393)	(206)	(140)	358	349

The Company also maintains cash and cash equivalent balances in other currencies in amounts that are not material.

NOTE 3 – FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk (cont.)

1) Concentration of currency risk (cont.)

Set forth below is certain data regarding dollar exchange rates:

	Exchange rate of NIS per $1	Exchange rate of Euro per $1
As of December 31:		
2019	3.456	0.891
2020	3.215	0.815
2021	3.110	0.884
Percentage increase (decrease) in the exchange rate:		
2020	(7.0)%	(8.5)%
2021	(3.3)%	8.5%

Set forth below is information on the linkage of monetary items:

	December 31, 2020			December 31, 2021		
	Dollar	NIS	Other currencies	Dollar	NIS	Other Currencies
		USD in thousands			USD in thousands	
Assets:						
Current assets:						
Cash and cash equivalents	12,488	3,755	588	7,223	4,699	1,068
Short term bank deposits	5,756	-	-	44,145	-	-
Other receivables	-	141	-	-	142	-
	18,244	3,896	588	51,368	4,841	1,068
Liabilities:						
Current liabilities:						
Current maturities of long-term loans	3,092	-	-	2,757	-	-
Accounts payable and accruals:						
Trade	2,455	518	2,945	2,700	442	2,425
Other	154	1,286	-	108	1,119	-
Non-current liabilities						
Long-term loans, net of current maturities	2,740	-	-	-	-	-
	8,441	1,804	2,945	5,565	1,561	2,425
Net balance	9,803	2,092	(2,357)	45,803	3,280	(1,357)

NOTE 3 – FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk (cont.)

2) Fair value of financial instruments

As of December 31, 2021, the financial instruments of the Company consist of non-derivative assets and liabilities (primarily working capital items, deposits and current loan), as well as warrants classified as a liability.

With regard to non-derivative assets and liabilities, given their nature, the fair value of the financial instruments included in working capital is generally close or identical to their carrying amount.

With regard to the warrants classified as a liability, see Note 11c. With regard to the long-term loan, see Note 10.

3) Exposure to market risk and management thereof

In the opinion of Company management, the market risk to which the Company is exposed is primarily related to currency risk exposure, as mentioned above. Additionally, Company management does not consider the interest rate risk mentioned in paragraph 4 below to be material.

4) Interest rate risk

Company management does not consider interest rate risk to be material, as the Company holds deposits and short-term government bonds whose fair value and/or cash flows are not materially affected by changes in interest rates.

b. Credit risk

Credit risk is managed at the Company level. These risks relate to cash and cash equivalents, bank deposits and other receivables.

The Company's cash, cash equivalents and short-term bank deposits at December 31, 2020, and 2021 were deposited with highly rated major Israeli and U.S. banks. In the Company's opinion, the credit risk associated with these balances is remote.

The Company considers its maximum exposure to credit risk to be as follows:

	December 31,	
	2020	2021
	in USD thousands	
Assets:		
Cash and cash equivalents	16,831	12,990
Short-term bank deposits	5,756	44,145
Other receivables	141	142
Total	22,728	57,277

NOTE 3 – FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (cont.)

c. Liquidity risk

Company management monitors rolling forecasts of the Company's liquidity reserves on the basis of anticipated cash flows and maintains the liquidity balances at a level that is sufficient to meet its needs.

Although the Company has succeeded in generating significant revenues from a number of out-licensing transactions in the past, it cannot determine with reasonable certainty if and when it will become profitable on a current basis. Management believes that the Company's current cash and other resources will be sufficient to fund its projected cash requirements into the first half of 2024. However, in the event that the Company does not begin to generate sustainable cash flows from its operating activities in the future, the Company will need to carry out significant cost reductions or raise additional funding.

d. Fair value of financial instruments

The different levels of valuation of financial instruments are defined as follows:

Level 1	Quoted prices (unadjusted) in active markets for identical assets or liabilities.
Level 2	Inputs, other than quoted prices included within level 1 that are observable for the asset or liability, either directly (as prices) or indirectly (derived from prices).
Level 3	Inputs for the asset or liability that are not based on observable market data (unobservable inputs).

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, and also considers counterparty credit risk, in its assessment of fair value. The fair value of the financial instruments included in the working capital of the Company, as well as the long-term loan, is usually identical or close to their carrying value. The fair value of the warrants is based on Level 3 measurements.

The fair value of the warrants, calculated based on the Black-Scholes model, was $1,859,000 as of December 31, 2021.

For more information on the parameters used to value the warrants, see Note 11c.

NOTE 3 – FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (cont.)

e. Changes in financial liabilities with cash flows included in financing activities

	Long-term loans	Warrants	Total
		in USD thousands	
Balance as of January 1, 2020	8,491	658	9,149
Changes during the year 2020:			
Cash flows received	-	5,669	5,669
Cash flows paid	(3,133)	-	(3,133)
Share premium resulting from exercise of warrants	-	(1,251)	(1,251)
Amounts recognized through profit and loss	474	5,142	5,616
Balance as of December 31, 2020	5,832	10,218	16,050
Changes during the year 2021:			
Cash flows paid	(3,376)	-	(3,376)
Share premium resulting from exercise of warrants	-	(10,295)	(10,295)
Amounts recognized through profit and loss	301	1,936	2,237
Balance as of December 31, 2021	2,757	1,859	4,616

See Note 9 for information on changes in lease liabilities.

f. Fair value measurement of warrants using significant unobservable inputs (level 3)

The following table presents the changes in level 3 instruments for the years ended December 31, 2019, 2020 and 2021:

	Warrants in USD thousands
Balance as of January 1, 2019	323
Changes during 2019:	
Issuances	4,969
Changes in fair value through profit and loss	(4,634)
Balance as of December 31, 2019	658
Changes during 2020:	
Issuances	5,669
Exercises	(1,251)
Changes in fair value through profit and loss	5,142
Balance as of December 31, 2020	10,218
Changes during 2021:	
Issuances	-
Exercises	(10,295)
Changes in fair value through profit and loss	1,936
Balance as of December 31, 2021	1,859

NOTE 4 – CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

As part of the financial reporting process, Company management is required to make estimates that affect the value of assets, liabilities, income, expenses and certain disclosures included in the Company's consolidated financial statements. By their very nature, such estimates are subjective and complex and consequently may differ from actual results.

The accounting estimates used in the preparation of the financial statements are continually evaluated and adjusted based on historical experience and other factors, including expectation of future events that are believed to be reasonable under the circumstances.

Described below are the critical accounting estimates used in the preparation of the financial statements, the formulation of which required Company management to make assumptions as to circumstances and events that involve significant uncertainty. In using its judgment to determine the accounting estimates, the Company takes into consideration, as appropriate, the relevant facts, past experience, the effect of external factors and reasonable assumptions under the circumstances.

Impairment of intangible assets

The Company performs impairment reviews of intangible assets on an annual basis, or more frequently if events or changes in circumstances indicate a potential impairment. In light of the clinical progress and additional expenses incurred with regard to the clinical development of BL-8040 and AGI-134, and following the valuation analysis performed as detailed in Note 8, the Company has concluded that the value of its intangible assets is higher than their carrying value as of December 31, 2020 and 2021.

Fair value estimations of warrants

As described in Notes 3d and 11, the Company completed financing transactions in which it issued ADSs and warrants to purchase additional ADSs. The fair value of the warrants, which are not traded on an active market, is determined by using valuation techniques. These valuation techniques maximize the use of observable market data where it is available and rely as little as possible on entity specific estimates.

NOTE 5 – CASH AND CASH EQUIVALENTS

	December 31,	
	2020	**2021**
	in USD thousands	
Cash on hand and in bank	5,549	8,461
Short-term bank deposits	11,282	4,529
	16,831	12,990

The short-term bank deposits included in cash and cash equivalents bear interest at annual rates of between 0.26% and 0.41%. The carrying amount of cash and cash equivalents approximates their fair value, since they bear interest at rates similar to prevailing market interest rates.

NOTE 6 – SHORT-TERM BANK DEPOSITS

The short-term bank deposits are in dollars and bear interest at annual rates of between 0.26% and 0.83%.

NOTE 7 – PROPERTY AND EQUIPMENT

Set forth below are the composition of property and equipment and the related accumulated depreciation, grouped by major classifications:

	Cost				Accumulated depreciation				Net book value December 31,	
	Balance at beginning of year	Additions during year	Deletions during year	Balance at end of year	Balance at beginning of year	Additions during year	Deletions during year	Balance at end of year	2020	2021
	in USD thousands				in USD thousands				in USD thousands	
Composition in 2021										
Office furniture and equipment	207	-	-	207	109	15	-	124	98	83
Computers and communications equipment	795	68	-	863	609	69	-	678	186	185
Laboratory equipment	1,561	29	-	1,590	1,351	158	-	1,509	210	81
Leasehold improvements	2,028	-	-	2,028	1,181	244	-	1,425	847	603
	4,591	97	-	4,688	3,250	486	-	3,736	1,341	952

NOTE 8 – INTANGIBLE ASSETS

The fair value of intellectual property has been calculated with the assistance of an external appraiser, based on the Company's estimates and assumptions. The value in use of the assets was estimated by using the decision-tree approach to valuing research products. This approach incorporates the option of abandonment at each development stage. The traditional Discounted Cash Flows (DCF) model is implemented at the final node of the decision tree. The DCF analysis estimates the future cash flows the Company expects to derive from the asset, and incorporates expectations about possible variations in the amount or timing of those future cash flows, and the uncertainty inherent in the assets. As of December 31, 2021 and 2020, the fair value of the intangible assets according to the impairment testing exceeds its book value. Therefore, no impairment was recognized.

Intellectual property includes the following intangible assets acquired by the Company:

- $6.7 million recorded as a result of the acquisition of Agalimmune (see Note 1a).
- $15.0 million ($10 million of cash consideration; $5 million of equity consideration) recorded as a result of an amendment to the in-licensing agreement with Biokine Therapeutics Ltd. ("Biokine") that reduced, for that consideration, future payments to be made by the Company on sublicense receipts (as defined in the license agreement) from 40% to 20%.

These assets are used for the Company's research and development activities and have not yet been amortized.

NOTE 8 – INTANGIBLE ASSETS (cont.)

Set forth below are the composition of intangible assets and the related accumulated depreciation, grouped by major classifications:

	Cost				Accumulated depreciation and impairment				Net book value	
	Balance at beginning of year	Additions during year	Deletions during year	Balance at end of year	Balance at beginning of year	Additions during year	Deletions during year	Balance at end of year	December 31, 2020	December 31, 2021
	in USD thousands				in USD thousands				in USD thousands	
Composition in 2021										
Intellectual property	21,792	-	-	21,792	96	-	-	96	21,696	21,696
Computer software	616	-	-	616	598	10	-	608	18	8
	22,408	-	-	22,408	694	10	-	704	21,714	21,704

NOTE 9 – LEASES

A. Right-of-use assets

	Cost				Accumulated depreciation				Net book value	
	Balance at beginning of year	Additions during year	Deletions during year	Balance at end of year	Balance at beginning of year	Additions during year	Deletions during year	Balance at end of year	December 31, 2020	December 31, 2021
	in USD thousands				in USD thousands				in USD thousands	
Composition in 2021										
Property	1,552	-	-	1,552	270	135	-	405	1,282	1,147
Motor vehicles	396	183	-	579	323	72	-	395	73	184
	1,948	183	-	2,131	593	207	-	800	1,355	1,331

NOTE 9 – LEASES (cont.)

B. Lease liabilities

	Balance at beginning of year	Additions during year	Deletions during year	Interest expense during year	Exchange differences during year	Payments during year	Balance at end of year
				in USD thousands			
Composition in 2021							
Property	1,733	-	-	228	54	(307)	1,708
Motor vehicles	119	183	-	16	1	(133)	186
	1,852	183	-	244	55	(440)	1,894

NOTE 9 – LEASES (cont.)

C. Additional disclosures

1) The Company leases its premises under a lease agreement entered into in August 2014. Payments under the lease commenced in June 2015, and the initial term of the lease expired in June 2020. The Company exercised its option to extend the lease through June 30, 2025, and has the option to extend the lease for two additional lease periods totaling up to five additional years, each option at a 5% increase to the preceding lease payment amount. The monthly lease fee is $26,000. In addition, the Company pays building maintenance charges of $9,400 per month.

2) The Company has entered into lease agreements in connection with a number of vehicles. The lease periods are generally for three years. The annual lease fees, linked to the CPI, are $250,000. To secure the terms of the lease agreements, the Company has prepaid approximately two months of lease payments to the leasing companies.

3) As of December 31, 2021, minimum future rental payments (taking into consideration the aforementioned extension periods) under the leases were as follows:

Year	Property	Motor vehicles	Total
		in USD thousands	
2022	324	97	421
2023	324	74	398
2024	340	43	383
2025	340	-	340
2026-2030	1,591	-	1,591
	2,919	214	3,133

Extension and termination options are included in most of the property and motor vehicle leases. These are used to maximize operational flexibility in terms of managing the assets used in the Company's operations. The substantial majority of extension and termination options are exercisable solely by the Company and not by the respective lessor.

NOTE 10 – LONG-TERM LOAN

In October 2018, the Company entered into a loan agreement with Kreos Capital V (Expert Fund) L.P. ("Kreos Capital") in order to finance a $10 million cash payment relating to the agreement with Biokine (see Note 8).

Composition

	December 31,	
	2020	2021
	in USD thousands	
Total loan balance	5,832	2,757
Less current maturities	(3,092)	(2,757)
Long-term portion of loan	2,740	-

NOTE 11 – EQUITY

a. Share capital

The Company's share capital is composed of ordinary shares, as follows:

	Number of Ordinary Shares	
	December 31,	
	2020	2021
Authorized share capital	1,500,000,000	1,500,000,000
Issued and paid-up share capital	349,169,545	715,156,008

	In USD and NIS Amounts	
	December 31,	
	2020	2021
Authorized share capital (in NIS)	150,000,000	150,000,000
Issued and paid-up share capital (in NIS)	34,916,955	71,515,600
Issued and paid-up share capital (in USD)	9,869,795	21,066,368

NOTE 11 – EQUITY (cont.)

b. Rights related to shares

The ordinary shares confer upon their holders voting and dividend rights and the right to receive assets of the Company upon its liquidation. As of December 31, 2020 and 2021, all outstanding share capital consisted of ordinary shares.

c. Changes in the Company's equity

1) In October 2018, the Company entered into a loan agreement with Kreos Capital. In connection with the loan, Kreos Capital received warrants to purchase 63,837 ADSs at an exercise price of $14.10 per ADS. The warrants issued have been classified as a non-current financial liability due to a net settlement provision. The warrant is exercisable for a period of ten years from the date of issuance.

   The fair value of the warrants at the date of issuance, computed using the Black-Scholes option pricing model, amounted to $861,000. The fair value of the warrants as of December 31, 2021 was $42,000 (December 31, 2020 - $55,000) and was based on the then current price of an ADS, a risk-free interest rate of 1.44%, an average standard deviation of 73.89%, and on the remaining contractual life of the warrants.

   The change in fair value for the years ended December 31, 2020 and 2021, of $8,000 and $13,000, respectively, has been recorded as non-operating income on the statement of comprehensive loss. As of December 31, 2021, none of these warrants had been exercised.

2) In February 2019, the Company completed an underwritten public offering of 1,866,667 of its ADSs and warrants to purchase 1,866,667 ADSs, at a public offering price of $8.25 per ADS and accompanying warrant. The warrants are exercisable immediately, expire five years from the date of issuance and have an exercise price of $11.25 per ADS. The offering raised a total of $15.4 million, with net proceeds of $14.1 million, after deducting fees and expenses. The amount of the offering consideration initially allocated to the warrants was $5.0 million. Total issuance costs initially allocated to the warrants were $0.4 million.

   The warrants issued have been classified as a non-current financial liability due to a net settlement provision. This liability was initially recognized at its fair value on the date the contract was entered into and is subsequently accounted for at fair value at each balance sheet date. The fair value changes are charged to non-operating income and expense in the statement of comprehensive loss.

   The fair value of the warrants as of December 31, 2021 was $564,000 (December 31, 2020 -$969,000), and was based on the then current price of an ADS, a risk-free interest rate of 0.73%, an average standard deviation of 95.7%, and on the remaining contractual life of the warrants.

   The changes in fair value for the years ended December 31, 2020 and 2021 of $377,000 and $405,000 have been recorded as non-operating expenses and non-operating income, respectively, on the statement of comprehensive loss.

   As of December 31, 2021, none of these warrants had been exercised.

NOTE 11 – EQUITY (cont.)

c. Changes in the Company's equity (cont.)

3) In May and June 2020, the Company sold in registered direct offerings an aggregate of 7,653,145 ADSs at a price of $1.75 per ADS. In concurrent private placements, the Company issued to investors in the offerings unregistered warrants to purchase 7,653,145 ADSs. The warrants are exercisable immediately, expire two and half years from the date of issuance and have an exercise price of $2.25 per ADS. In addition, the Company granted to the placement agent's designees, as part of the placement fees, warrants to purchase 382,657 ADSs. These warrants are exercisable immediately, expire two and half years from the date of issuance and have an exercise price of $2.1875 per ADS. The offerings raised a total of $13.4 million, with net proceeds of $12.0 million, after deducting fees and expenses. The amount of the offering consideration initially allocated to the warrants was $5.7 million. Total issuance costs initially allocated to the warrants were $0.6 million.

   The warrants issued have been classified as a non-current financial liability due to a net settlement provision. This liability was initially recognized at its fair value on the date the contract was entered into and is subsequently accounted for at fair value at each balance sheet date. The fair value changes are charged to non-operating income and expense in the statement of comprehensive loss.

   As of December 31, 2020 and 2021, 875,000 and 4,864,741 of these warrants had been exercised.

   The fair value of the unexercised warrants as of December 31, 2021 was $1,253,000 (December 31, 2020 - $9,194,000) and was based on the then current price of an ADS, a risk-free interest rate of 0.39%, an average standard deviation of 80.8% and on the remaining contractual life of the warrants.

   The changes in fair value for the years ended December 31, 2020 and 2021 of $4,776,000 and $2,354,000 have been recorded as non-operating expenses, respectively, on the statement of comprehensive loss.

4) In January 2021, the Company completed an underwritten public offering of 14,375,000 of its ADSs at a public offering price of $2.40 per ADS. The offering raised total gross proceeds of $34.5 million, with net proceeds of $31.4 million after deducting fees and expenses. In addition, warrants to purchase 718,750 ADSs were granted to the underwriters. These warrants are exercisable immediately, expire five years from the date of issuance and have an exercise price of $3.00 per ADS.

   The warrants have been classified as shareholders' equity, with initial recognition at fair value on the date issued. The total issuance costs initially allocated to the warrants were recorded as an offset to share premium.

   The fair value of the warrants on the issuance date was approximately $1.0 million, which was recorded as issuance costs, and computed using the Black and Scholes option pricing model, based upon the then current price of an ADS, a risk-free interest rate of approximately 0.45% and an average standard deviation of approximately 73.8%.

NOTE 11 – EQUITY (cont.)

d. Share purchase agreements

1) In September 2020, the Company entered into an ATM sales agreement with H.C. Wainwright & Co., LLC ("HCW"), pursuant to which the Company was entitled, at its sole discretion, to offer and sell through HCW, acting as sales agent, ADSs having an aggregate offering price of up to $25.0 million throughout the period during which the ATM facility remained in effect. The Company agreed to pay HCW a commission of 3.0% of the gross proceeds from the sale of ADSs under the facility. Expenses associated with establishment of the ATM facility with HCW, amounting to $0.2 million, were recorded in 2020 as non-operating expenses. In September 2021, the Company terminated the agreement. During 2021, the Company issued a total of 4,745,368 ADSs under the agreement for total gross proceeds of $18.5 million. From the effective date of the agreement through its termination, 7,381,101 ADSs were sold under the program for total gross proceeds of approximately $24.5 million.

2) In September 2021, the Company entered into a new $25.0 million ATM sales agreement with HCW under substantially identical terms to the previous agreement. Expenses associated with establishment of the ATM facility with HCW, amounting to $0.1 million, were recorded in non-operating expenses during the period. From the effective date of the new agreement through the issuance date of this report, 402,327 ADSs were sold under the program for total gross proceeds of approximately $1.1 million.

e. Share-based payments

1) Share Incentive plan – general

In 2003, the Company adopted the 2003 Share Incentive Plan (the "Plan"). The Plan provides for the granting of stock options and ordinary shares to the Company's employees, directors, consultants and other service providers. Options are issued at the determination of the Board of Directors in accordance with applicable law. The options are generally exercisable for a ten-year period and the grants generally vest over a four-year period. In 2013, the Company's Board of Directors approved amendments to the Plan to take into account changes in laws and regulations that had occurred since its adoption and to extend the term of the plan until November 2023. In 2016, the Board of Directors approved amendments to the Plan to allow the grant of restricted stock units ("RSUs") and performance stock units ("PSUs").

PSUs are RSUs that are linked to any one or more performance goals (in addition to, or in lieu of, time-based vesting terms) determined appropriate by the Board of Directors. The specific performance goals, as well as the time period associated with achieving such goals, are approved by the Board and are set forth in the grantee's grant agreement. To date, each PSU grant has had between three to five performance goals on which vesting is based, each such goal being either a specified Company milestone and or the success of a specific project, with vesting of 20-40% on the achievement of each goal. The tranche of PSUs associated with a given milestone expires 12 months after the target date established for that milestone. During 2021, 514,151 PSUs were vested in accordance with their original terms.

NOTE 11 – EQUITY (cont.)

e. Share-based payments (cont.)

1) Share Incentive plan – general (cont.)

As of December 31, 2021, there were 43,801,214 ordinary shares issuable upon the exercise of outstanding equity instruments under the Plan.

Company employees and directors are granted options under Section 102 of the Israeli Income Tax Ordinance (the "Ordinance"), primarily under the "capital gains" track. Non-employees of the Company (consultants and other service providers) are granted options under Section 3(i) of the Ordinance.

As of December 31, 2021, there were 5.7 million remaining authorized but unissued ordinary shares in the pool reserved for future share-based incentive grants.

2) Employee share incentive plan:

The following table contains additional information concerning equity instruments granted to employees and directors under the existing share incentive plans.

	Year ended December 31,					
	2019		2020		2021	
	Number of options	Weighted average exercise price (in NIS)	Number of options	Weighted average exercise price (in NIS)	Number of options	Weighted average exercise price (in NIS)
Outstanding at beginning of year	11,459,697	4.2	19,358,913	2.6	35,981,579	1.5
Granted	11,057,600	1.3	18,689,300	0.5	6,588,200	0.4
Forfeited and expired	(3,084,834)	3.9	(1,776,037)	2.2	(1,438,642)	3.0
Exercised	(73,550)	0.1	(290,597)	0.1	(174,923)	0.1
Outstanding at end of year*	19,358,913	2.6	35,981,579	1.5	40,956,214	0.7**
Exercisable at end of year	5,353,089	5.1	11,535,679	3.2	18,663,353	1.7

* As of December 31, 2019, 2020 and 2021, includes 2,225,704, 2,421,799 and 4,084,748 PSUs at an exercise price of 0.10 NIS (par value of ordinary shares), for which performance obligations have not been met.

** See 3 below.

NOTE 11 – EQUITY (cont.)

e. Share-based payments (cont.)

2) Employee share incentive plan (cont.):

The total consideration received from the exercise of equity instruments during 2019, 2020 and 2021 was not material.

Set forth below is data regarding the range of exercise prices and weighted-average remaining contractual life (in years) for the equity instruments outstanding at the end of each of the years indicated.

	As of December 31,					
	2019		2020		2021	
Range of exercise prices (in NIS)	Number of options outstanding	Weighted average remaining contractual life (in yrs.)	Number of options outstanding	Weighted average remaining contractual life (in yrs.)	Number of options outstanding	Weighted average remaining contractual life (in yrs.)
Up to 2.00	11,676,900	9.9	28,888,767	9.3	40,276,214	8.0
2.01-5.00	6,341,033	7.3	5,866,532	6.3	630,000	5.2
5.01-10.00	822,300	3.9	707,600	3.1	50,000	0.2
10.01-20.00	518,680	3.2	518,680	1.9	-	-
	19,358,913	8.6	35,981,579	8.6	40,956,214	8.0

The fair value of equity instruments granted to employees through December 31, 2021 has been determined using the Black-Scholes option-pricing model. These values are based on the following assumptions as of the applicable grant dates:

	2019	2020	2021
Expected dividend yield	0%	0%	0%
Expected volatility	61%	63%	67%
Risk-free interest rate	3%	1%	1%
Expected life of options (in years)	6	6	6

The remaining unrecognized deferred compensation expense as of December 31, 2021 was $1.1 million. This amount will be expensed over the remaining vesting period of the equity instruments.

NOTE 11 – EQUITY (cont.)

e. Share-based payments (cont.)

3) Repricing of employee stock options

In September 2020, the Board of Directors approved the re-pricing of outstanding "underwater" employee stock options for the purchase of 12.3 million ordinary shares, out of total employee stock options for the purchase of 15.1 million ordinary shares outstanding at that time. The weighted average exercise price of the options subject to re-pricing was NIS 2.64 per share, with the proposed new exercise price of the options at NIS 1.00 per share. Execution of the re-pricing was subject to approval from the Israeli tax authorities, which was received in January 2021. The total compensation cost associated with the re-pricing of approximately $200,000 has been recorded as an expense beginning in 2021 and will continue over the remaining vesting period of the re-priced options.

4) Stock options to consultants

From inception through December 31, 2018, the Company issued to consultants options for the purchase of 371,523 ordinary shares at a weighted average exercise price of NIS 7.86 per share.

In 2019, the Company issued additional options to consultants for the purchase of 225,000 ordinary shares at a weighted average price of NIS 0.90 per share.

In 2020, the Company did not issue additional options to consultants.

In 2021, the Company issued additional options to consultants for the purchase of 2,700,000 ordinary shares at a weighted average price of NIS 0.66 per share.

The options to consultants generally vest over four years and may be exercised for periods of between five and ten years. As of December 31, 2021, 2,845,000 options to consultants were outstanding with a weighted average exercise price of NIS 1.05 per share and a weighted average contractual life of 8.6 years.

Company management estimates the fair value of the options granted to consultants based on the value of services received over the vesting period of the applicable options. The value of such services (primarily in respect of clinical advisory services) is estimated based on the additional cash compensation the Company would need to pay if such options were not granted. The value of services recorded in each of the years 2019, 2020 and 2021 was not material.

NOTE 12 – TAXES ON INCOME

a. Corporate taxation in Israel

The taxable income of BioLineRx, not subject to benefits as detailed below, is taxed at the standard Israeli corporate tax rate, which was 23% for all years included in these financial statements. Under amendment no. 73 to the Encouragement of Capital Investment Law, a portion of the Company's taxable income in Israel is entitled to a preferred 12% tax rate on its income derived from intellectual property.

b. Tax loss carryforwards

As of December 31, 2021, the tax loss carryforwards of BioLineRx were approximately $325 million. The tax loss carryforwards have no expiration date.

The Company has not created deferred tax assets in respect of these tax loss carryforwards. See Note 2(1).

c. Tax assessments

In accordance with Israeli tax regulations, the tax returns filed by BioLineRx through the 2016 tax year are considered final.

d. Theoretical taxes

As described in Note 2, paragraph 1, the Company has not recognized any deferred tax assets in the financial statements, as it does not expect to generate taxable income in the foreseeable future. The reported tax on the Company's income before taxes differs from the theoretical amount that would arise using the weighted average tax rate applicable to income of the consolidated entities as follows:

	Year ended December 31,					
	2019		2020		2021	
		in USD thousands		in USD thousands		in USD thousands
Loss before taxes	23.0%	(25,446)	23.0%	(30,021)	23.0%	(27,045)
Theoretical tax benefit		(5,853)		(6,905)		(6,220)
Disallowed deductions (tax exempt income):						
Loss (gain) on adjustment of warrants to fair value		(1,054)		1,280		480
Share-based compensation		405		292		343
Other		10		11		11
Increase in taxes for tax losses and timing differences incurred in the reporting year for which deferred taxes were not created		6,492		5,322		5,386
Taxes on income for the reported year		-		-		-

NOTE 13 – LOSS PER SHARE

The following table contains the data used in the computation of the basic loss per share:

	Year ended December 31,		
	2019	**2020**	**2021**
		in USD thousands	
Loss attributed to ordinary shares	(25,446)	(30,021)	(27,054)
		in thousands	
Number of shares used in basic calculation	146,407	252,844	662,934
		in USD	
Basic and diluted loss per ordinary share	(0.17)	(0.12)	(0.04)

All outstanding options and warrants have been excluded from the calculation of the diluted loss per share for all years presented, since their effect was anti-dilutive.

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES

a. Commitments

1) Obligation to pay royalties to the State of Israel

The Company is required to pay royalties to the State of Israel (represented by the Israel Innovation Authority, or IIA), computed on the basis of proceeds from the sale or license of products whose development was supported by grants from the predecessor of the IIA, the Office of the Chief Scientist. This obligation relates solely to financial participation in the development of products by the Company.

In accordance with the terms of grants provided by the IIA, the State is entitled to royalties on the sale or license of any product whose development was supported with State participation. These royalties are generally 3% in the first three years from initial repayment, 4% of sales in the three subsequent years and 5% of sales in the seventh year until repayment of 100% of the grants (linked to the dollar) received by the Company, plus annual interest at the LIBOR rate. Under certain circumstances, the royalty rate is calculated according to a formula based on the ratio of participation by the IIA in the project to the total project costs incurred by the Company

In connection with the in-licensing of BL-8040 from Biokine Therapeutics Ltd. (“Biokine”), and as a condition to IIA consent to the transaction, the Company agreed to abide by any obligations resulting from funds previously received by Biokine from the IIA. The contingent liability to the IIA assumed by the Company relating to this transaction amounts to $3.6 million as of December 31, 2021. The Company has a full right of offset for amounts payable to the IIA from payments due to Biokine in the future.

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

2) Licensing agreements

From time to time, the Company enters into in-licensing agreements with academic institutions, research institutions and companies (the "licensors") in connection with the development of therapeutic compounds. Pursuant to these licensing agreements, the Company generally obtains the rights for one or more therapeutic compounds in pre-clinical and early clinical stages of development, in order to continue development of the compounds through more advanced stages of development and, subsequently, to manufacture, distribute and market the drugs or to out-license the development, manufacturing and commercialization rights to third parties. Such development activities are carried out by either the Company and/or by companies or institutions to which the Company has entered into an out-license agreement, subject to certain restrictions stipulated in the various agreements.

The licenses that have been granted to the Company are broad and comprehensive, and generally include various provisions and usage rights as follows: (i) territorial scope of the license (global); (ii) term of the license (unrestricted but not shorter than the life of the patent); and (iii) development of the therapeutic compound (allowing the Company to perform all development activities on its own, or by outsourcing under Company supervision, as well as out-licensing development under the license to other companies, subject to the provisions of the licensing agreements).

According to the provisions of the licensing agreements, the intellectual property rights in the development of any licensed technology, through the date the applicable license agreement is effective, remain with the licensor, while the rights in products and/or other deliverables developed by the Company after the license is granted belong to the Company. In cases where the licensor has a claim to an invention that was jointly developed with the Company, the licensor also co-owns the related intellectual property. In any event, the scope of the license also covers these intellectual property rights.

In addition, the Company generally undertakes in the licensing agreements to protect registered patents resulting from developments under the various licenses, to promote the registration of patents covering new developments in cooperation with the licensor, and to bear responsibility for all related costs. Pursuant to the various agreements, the Company generally works to register the various patents on a broad basis worldwide, and if the Company decides not to initiate or continue a patent registration proceeding in a given country, the Company is required to notify the applicable licensor to this effect and the licensor is entitled to take action for registration of the patent in such country.

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

2) Licensing agreements (cont.)

The consideration paid pursuant to the licensing agreements generally includes several components that may be payable over the license period and that relate, inter alia, to the progress made in research and development activities, as well as commercial success, as follows: (a) one-time, up-front payment and/or periodic payments; (b) payments through the early stages of development (i.e., through the end of phase 2); (c) payments upon the achievement of milestones necessary for advancing to phase 3; (d) payments from the end of a successful phase 3 trial through approval of the therapeutic compound; and e) royalties on sales of the final product resulting from development under the license or including any component thereof, generally less than 5% of the Company's net sales of the product, although in specific instances the royalty rate has been higher or lower than this range. In instances where the Company has out-licensed the product for further development, the Company pays a percentage of the net consideration received from the licensee ("Sublicense Receipts") to the upstream licensor that generally range from 20% to 29.5% of such consideration, although in specific instances the percentage paid has been higher or lower than this range. These Sublicense Receipts generally take the place of most or all of the milestone and royalty payments set forth in (b) through (e) above.

The license agreements may be cancelled by the licensor only in specific circumstances, generally upon the occurrence of one of the following events: (a) the Company's failure to meet certain milestones stipulated in the applicable license agreement and appended timetables; (b) default, insolvency, receivership, liquidation, etc. of the Company that is not imposed and/or lifted within the timeframe stipulated in the license agreement; and (c) fundamental breach of the license agreement that is not corrected within the stipulated timeframe. The Company may generally cancel a license agreement with prior notice of 30 to 90 days, due to unsuccessful development or any other cause.

The Company has undertaken to indemnify certain licensors, their employees, officers, representatives or anyone acting on their behalf for any damage and/or expense that they may incur in connection with the Company's use of a license granted to it, all in accordance with the terms stipulated in the applicable license agreements.

Some of the license agreements are accompanied by consulting, support and cooperation agreements, pursuant to which the Company is committed to pay the various licensers a fixed monthly amount over the period stipulated in the agreement for their assistance in the continued research and development under the license.

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

3) Commitments in respect of Agalimmune and Biokine

The consideration due to Agalimmune shareholders is based on certain development and commercial milestones, including future sales of Agalimmune products. In addition, the selling shareholders of Agalimmune have certain reversionary rights in the event of a breach of the transaction agreement and certain other limited triggering events.

In accordance with the license agreement of BL-8040 with Biokine (as amended), the Company is required to pay Biokine a payment of 20% of amounts received as consideration in connection with any sublicensing or sale of the licensed technology. Biokine is also eligible to receive up to a total of $5 million in future milestone payments. Subject to certain limitations, if the Company independently sell products related to BL-8040, the Company will pay Biokine a royalty payment of 10% of net sales.

4) Purchase orders

The Company's outstanding open purchase order commitments as of December 31, 2021 amounted to $8.4 million.

b. Guarantees

To secure the Company's lease obligation on its premises, the Company has provided a bank guarantee in the amount of $100,000 for the benefit of the lessor, which remains outstanding as of December 31, 2021.

NOTE 15 – TRANSACTIONS AND BALANCES WITH RELATED PARTIES

Transactions with related parties

Expenses:

	Year ended December 31,		
	2019	2020	2021
		in USD thousands	
Benefits to related parties:			
Compensation and benefits to senior management, including benefit component of equity instrument grants	1,934	2,391	2,302
Compensation and benefits to directors, including benefit component of equity instrument grants	280	373	300

Key management compensation

Key management includes directors and executive officers. The compensation paid or payable to key management for services during each of the years indicated is presented below.

	Year ended December 31,		
	2019	2020	2021
		in USD thousands	
Salaries and other short-term employee benefits	1,415	1,656	1,883
Post-employment benefits	115	126	136
Other long-term benefits	31	33	35
Share-based compensation	653	949	548
	2,214	2,764	2,602

NOTE 16 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

a. Other receivables

	December 31,	
	2020	2021
	in USD thousands	
Government institutions	139	140
Other	2	2
	141	142

b. Accounts payable and accruals

		December 31,	
		2020	2021
		in USD thousands	
1)	Trade:		
	Accounts payable:		
	Overseas	4,795	4,504
	In Israel	1,123	1,063
		5,918	5,567
2)	Other:		
	Accrued expenses	884	521
	Accrual for vacation and recreation pay	287	397
	Payroll and related expenses	266	307
	Other	3	2
		1,440	1,227

The carrying amounts of accounts payable and accruals approximate their fair value, as the effect of discounting is not material.

NOTE 16 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

c. Research and development expenses

	Year ended December 31,		
	2019	2020	2021
	in USD thousands		
Research and development services	16,029	11,696	12,088
Payroll and related expenses	3,784	3,501	4,074
Share based compensation	1,233	623	971
Lab, occupancy and telephone	782	771	882
Professional fees	464	643	595
Depreciation and amortization	862	864	660
Other	284	75	196
	23,438	18,173	19,466

d. Sales and marketing expenses

	Year ended December 31,		
	2019	2020	2021
	in USD thousands		
Marketing	296	585	729
Payroll and related expenses	503	234	249
Overseas travel	58	21	25
	857	840	1,003

e. General and administrative expenses

	Year ended December 31,		
	2019	2020	2021
	in USD thousands		
Payroll and related expenses	1,416	1,369	1,408
Share based compensation	465	729	583
Professional fees	1,193	1,044	1,103
Insurance	298	603	1,064
Depreciation	78	70	42
Other	366	99	108
	3,816	3,914	4,308

NOTE 16 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

f. Non-operating income (expenses), net

	Year ended December 31,		
	2019	**2020**	**2021**
	in USD thousands		
Issuance costs	(417)	(784)	-
Changes in fair value of warrants	4,634	(5,142)	(1,936)
Other	(52)	225	106
	4,165	(5,701)	(1,830)

g. Financial income

	Year ended December 31,		
	2019	**2020**	**2021**
	in USD thousands		
Interest income and exchange differences	777	236	559
	777	236	559

h. Financial expenses

	Year ended December 31,		
	2019	**2020**	**2021**
	in USD thousands		
Interest expense and exchange differences	2,253	1,607	984
Bank commissions	24	22	22
	2,277	1,629	1,006

Exhibit 4.16

[final paragraph Section 3.4]

The Company is authorized to purchase insurance policies (including run-off policies) to cover the liability of directors and Executives that are currently in office and that shall be in office from time to time, including directors and Executives that may have a controlling interest in the Company (if such becomes applicable in the future), within the following limits~~:~~ ~~- (a) the premium for each policy period shall be not more than $250,000; (b)~~ the maximum aggregate limit of liability pursuant to the policies shall be not more than $20 million for each insurance. ~~period ; and (c) the maximum deductible shall be not more than $250,000.~~ The Compensation Committee shall be authorized to increase the coverage purchased~~, and/or the premium paid for such policies~~, by up to 20% in any year, as compared to the previous year, or cumulatively for a number of years, without an additional shareholders' approval to the extent permitted under the Companies Law. The authority to enter into such insurance policies shall be held by the Compensation Committee, provided that the premium for each policy, the maximum deductible and the terms of the contract are consistent with market conditions and will not materially affect the Company's profits, property or liabilities.

5.3 In exceptional circumstances (e.g., a key opinion leader or globally recognized expert), higher compensation may be paid to a director candidate in accordance with this Policy and applicable law. Notwithstanding the above, in the case of a chairperson determined by the Board to be an active chairperson the financial compensation may be up to 50% higher than for other directors (other than those directors who may receive greater compensation due to the exceptional circumstances as described in this paragraph).

5.4 The Compensation Committee may propose, and Board may approve, the grant of equity to directors, in accordance with the provisions set forth in Section 4.2 to this Policy, which shall apply mutatis mutandis, taking into consideration compliance with this Policy and applicable law.

Exhibit 4.18

Certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. [*] indicates that information has been redacted.

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT
(FOR PANCREATIC CANCER STUDY)
(as amended)

This CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT (this "**Agreement**"), made as of January 11, 2016 (the "**Effective Date**"), is by and between Merck Sharp & Dohme B.V., having a place of business at Waarderweg 39, 2031 BN Haarlem, Netherlands ("**Merck**") and BioLineRx Ltd., having a place of business at Modi'in Technology Park, 2 HaMa'ayan Street, Modi'in 7177871, Israel ("**BioLineRx**"). Merck and BioLineRx are each referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

A. BioLineRx is developing the BioLineRx Compound (as defined below) for the treatment of certain tumor types.

B. Merck is developing the Merck Compound (as defined below) for the treatment of certain tumor types.

C. BioLineRx desires to sponsor a clinical trial in which the BioLineRx Compound and the Merck Compound would be dosed concurrently or in combination.

D. Merck and BioLineRx, consistent with the terms of this Agreement, desire to collaborate as more fully described herein, including by providing the Merck Compound and the BioLineRx Compound for the Study (as defined below).

NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, mutually agree as follows:

1. Definitions.

For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

1.1 "**Affiliate**" means, with respect to either Party, a firm, corporation or other entity which directly or indirectly owns or controls said Party, or is owned or controlled by said Party, or is under common ownership or control with said Party. As used in this Section 1.1, the word "**control**" means (i) the direct or indirect ownership of more than fifty percent (50%) of the outstanding voting securities of a legal entity, or (ii) possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.

1.2 "**Agreement**" means this agreement, as amended by the Parties from time to time, and as set forth in the preamble.

1.3 "**Alliance Manager**" has the meaning set forth in Section 3.10.

1.4 "**Applicable Law**" means all federal, state, local, national and regional statutes, laws, rules, regulations and directives applicable to a particular activity hereunder, including performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect from time to time, including those promulgated by the United States Food and Drug Administration ("**FDA**"), national regulatory authorities, the European Medicines Agency ("**EMA**") and any successor agency to the FDA or EMA or any agency or authority performing some or all of the functions of the FDA or EMA in any jurisdiction outside the United States or the European Union (each a "**Regulatory Authority**" and collectively, "**Regulatory Authorities**"), and including cGMP and GCP (each as defined below); all data protection requirements such as those specified in the EU Data Protection Directive and the regulations issued under the United States Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"); export control and economic sanctions regulations which prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals; anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; laws and regulations governing payments to healthcare providers; and any United States or other country's or jurisdiction's successor or replacement statutes, laws, rules, regulations and directives relating to the foregoing.

1.5 "**BioLineRx**" has the meaning set forth in the preamble.

1.6 [Deleted]

1.7 "**BioLineRx Class Compound**" means any small or large molecule that [*]

1.8 "**BioLineRx Compound**" means BioLineRx's BL-8040, a short synthetic peptide, which is a CXCR4 inhibitor.

1.9 "**BioLineRx Inventions**" is defined in Section 10.2.

1.10 "**Business Day**" means any day other than a Friday (in the case of BioLineRx), Saturday, Sunday, or a day on which commercial banks located in the country where the applicable obligations are to be performed are authorized or required by law to be closed.

1.11 "**cGMP**" means the current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Compounds.

1.12 "**Clinical Data**" means all data (including raw data) and results generated by or on behalf of either Party or at either Party's direction, or by or on behalf of the Parties together or at their direction, in the course of each such Party's performance of the Study; excluding, however, Sample Testing Results.

1.13 "**Clinical Quality Agreement**" has the meaning set forth in Section 8.2.

1.14 "**CMC**" means "Chemistry Manufacturing and Controls" as such term of art is used in the pharmaceutical industry.

1.15 "**Compounds**" means the BioLineRx Compound and the Merck Compound. A "**Compound**" means either the BioLineRx Compound or the Merck Compound, as applicable.

1.16 "**Combination**" means the use or method of using the BioLineRx Compound and the Merck Compound in concomitant or sequential administration.

1.17 "**Confidential Information**" means any information, Know-How or other proprietary information or materials furnished to one Party ("**Receiving Party**") by or on behalf of the other Party ("**Disclosing Party**") pursuant to this Agreement, except to the extent that such information or materials: (a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party, as demonstrated by competent evidence; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; (d) was disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or (e) was subsequently developed by the Receiving Party without use of the Disclosing Party Confidential Information, as demonstrated by competent evidence.

1.18 "**Continuing Party**" has the meaning set forth in Section 10.1.3.

1.19 "**Control**" or "**Controlled**" means, with respect to particular information or intellectual property, that the applicable Party owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense to the other Party as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.20 "**CTA**" means an application to a Regulatory Authority for purposes of requesting the ability to start or continue a clinical trial.

1.21 "**Data Sharing and Sample Testing Schedule**" means the schedule attached hereto as Schedule I.

1.22 "**Defending Party**" has the meaning set forth in Section 14.2.3.

1.23 "**Delivery**" has the meaning set forth in Section 8.4.1.

1.24 "**Direct Manufacturing Costs**" has the meaning set forth in Section6.12.

1.25 "**Disposition Package**" has the meaning set forth in Section 8.8.1.

1.26 "**Dispute**" has the meaning set forth in Section 22.1.

1.27 "**Effective Date**" has the meaning set forth in the preamble.

1.28 "**EMA**" has the meaning set forth in the definition of Applicable Law.

1.29 "**Exclusion List**" has the meaning set forth in the definition of Violation.

1.30 "**FDA**" has the meaning set forth in the definition of Applicable Law.

1.31 "**Filing Party**" has the meaning set forth in Section 10.1.3.

1.32 "**Force Majeure**" has the meaning set forth Section 16.

1.33 "**GAAP**" has the meaning set forth in Section 6.12.

1.34 "**GCP**" means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Compounds.

1.35 "**Government Official**" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any Person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organization such as the World Bank or United Nations; (e) any officer or employee of a political party or any Person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to make decisions with the potential to affect the business of either of the Parties.

1.36 "**HIPAA**" has the meaning set forth in the definition of Applicable Law.

1.37 "**IND**" means any Investigational New Drug Application filed or to be filed with the FDA as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and/or the equivalent application in the jurisdictions outside the United States, including an "Investigational Medicinal Product Dossier" filed or to be filed with Regulatory Authorities in the European Union.

1.38 "**Indirect Manufacturing Costs**" has the meaning set forth in Section 6.12.

1.39 "**Inventions**" means all inventions and discoveries, whether or not patentable, that are made, conceived, or first actually reduced to practice by or on behalf of a Party, or by or on behalf of the Parties together, (i) in the design or performance of the Study, or in the design or performance of any Phase III registration study for the Combination performed pursuant to Section 3.14, or (ii) through use of any unpublished Clinical Data or Sample Testing Results.

1.40 "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 3.10.

1.41 "**Joint Patent Application**" has the meaning set forth in Section 10.1.3.

1.42 "**Joint Patent**" means a patent that issues from a Joint Patent Application.

1.43 "**Jointly Owned Invention**" has the meaning set forth in Section 10.1.1.

1.44 "**Know-How**" means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

1.45 "**Liability**" has the meaning set forth in Section 14.2.1.

1.46 "**Manufacture**," "**Manufactured**," or "**Manufacturing**" means all activities related to the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.

1.47 "**Manufacturer's Release**" or "**Release**" has the meaning ascribed to such term in the Clinical Quality Agreement.

1.48 "**Manufacturing Costs**" has the meaning set forth in Section 6.12.

1.49 "**Manufacturing Site**" means the facilities where a Compound is Manufactured by or on behalf of a Party, as such Manufacturing Site may change from time to time in accordance with Section 8.7.

1.50 "**Merck**" has the meaning set forth in the preamble.

1.51 [Deleted]

1.52 "**Merck Compound**" means pembrolizumab, a humanized anti-human PD-1 monoclonal antibody [*]

1.53 "**Merck Inventions**" is defined in Section 10.3.

1.54 "**NDA**" means a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the United States Federal Food, Drug and Cosmetic Act, or similar application or submission for a marketing authorization of a product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

1.55 "**Non-Conformance**" means, with respect to a given unit of Compound, (i) a deviation from an approved cGMP requirement with respect to the applicable Compound, such as a procedure, Specification, or operating parameter, or a circumstance that requires an investigation to assess impact to the quality of the applicable Compound or (ii) that such Compound failed to meet the applicable representations and warranties set forth in Section 2.3. Classification of the Non-Conformance is detailed in the Clinical Quality Agreement.

1.56 "**Non-Filing Party**" has the meaning set forth in Section 10.1.3.

1.57 "**Opting-out Party**" has the meaning set forth in Section 10.1.3.

1.58 "**Other Party**" has the meaning set forth in Section 14.2.3.

1.59 "**Party/Parties**" has the meaning set forth in the preamble.

1.60 "**PD-1 Antagonist**" means any small or large molecule that [*].

1.61 "**Permitted Use**" has the meaning set forth in Section 3.7.

1.62 "**Person**" means any individual, sole proprietorship, partnership, corporation, business trust, joint stock company, trust, unincorporated organization, association, limited liability company, institution, public benefit corporation, joint venture, entity or governmental entity.

1.63 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 5.1.

1.64 "**Project Manager**" has the meaning set forth in Section 3.10.

1.65 "**Protocol**" means the written documentation that describes the Study and sets forth specific activities to be performed as part of the Study conduct, to be finalized and agreed upon within sixty (60) calendar days after the Effective Date pursuant to Section 4.1.

1.66 "**Regulatory Approvals**" means, with respect to a Compound, any and all permissions (other than the Manufacturing approvals) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration, importation, sale and distribution of such Compound in the United States, Europe or other applicable jurisdictions for use in the Study.

1.67 "**Regulatory Documentation**" means, with respect to the Compounds, all submissions to Regulatory Authorities in connection with the development of such Compounds, including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents that include Clinical Data).

1.68 "**Regulatory Authorities**" has the meaning set forth in the definition of Applicable Law.

1.69 "**Related Agreements**" means the Pharmacovigilance Agreement and the Clinical Quality Agreement.

1.70 "**Right of Reference**" means the "right of reference" defined in 21 CFR 314.3(b), including with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to a Party's Compound, only to the extent necessary for the conduct of the Study in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder.

1.71 "**SAEs**" has the meaning set forth in Section 5.1.

1.72 "**SADRs**" has the meaning set forth in Section 5.1.

1.73 "**Samples**" means biological specimens collected from subjects participating in the Study, including urine, blood and tissue samples.

1.74 "**Sample Testing**" means the analyses to be performed by each Party using the applicable Samples, as described in the Data Sharing and Sample Testing Schedule (Schedule I).

1.75 "**Sample Testing Results**" means those results arising from the Sample Testing which are shared between Merck and BioLineRx, as set forth in the Data Sharing and Sample Testing Schedule.

1.76 "**Specifications**" means, with respect to a given Compound, the set of requirements for such Compound as set forth in the Clinical Quality Agreement.

1.77 "**Study**" means a Phase IIa clinical trial carried out in accordance with the Protocol to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of the concomitant and/or sequenced administration of the Merck Compound and the BioLineRx Compound in subjects with pancreatic cancer.

1.78 "**Study Completion**" has the meaning set forth in Section 3.11.

1.79 "**Subcontractors**" has the meaning set forth in Section 2.4.

1.80 "**Term**" has the meaning set forth in Section 6.1.

1.81 "**Territory**" means anywhere in the world.

1.82 "**Third Party**" means any Person or entity other than BioLineRx, Merck or their respective Affiliates.

1.83 "**VAT**" has the meaning set forth in Section 8.16.

1.84 "**Violation**" means that a Party or any of its officers or directors or any other personnel (or other permitted agents of a Party performing activities hereunder) has been: (1) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (http://oig.hhs.gov /exclusions/authorities.asp); (2) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (http://exclusions.oig.hhs.gov/) or listed as having an active exclusion in the System for Award Management (http://www.sam.gov); or (3) listed by any US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a (http://www.fda.gov/ora/compliance_ref/debar/) (each of (1), (2) and (3) collectively the "**Exclusions Lists**").

2 Scope of the Agreement.

2.1 *Generally*. Each Party shall contribute to the Study such resources as are necessary to fulfill its obligations set forth in this Agreement and more specifically described in Article 7.

2.2 *Obligations*. Each Party shall act in good faith in performing its obligations under this Agreement and each Related Agreement, and shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of its Compound as contemplated by this Agreement.

2.3 *Compound Commitments*. BioLineRx shall Manufacture and supply the BioLineRx Compound for purposes of the Study in accordance with Article 8, and BioLineRx hereby represents and warrants to Merck that, at the time of Delivery of the BioLineRx Compound, such BioLineRx Compound shall have been Manufactured and supplied in compliance with: (i) the Specifications for the BioLineRx Compound; (ii) the Clinical Quality Agreement; and (iii) all Applicable Law, including cGMP and health, safety and environmental protections. Merck shall Manufacture and supply the Merck Compound for purposes of the Study in accordance with Article 8, and Merck hereby represents and warrants to BioLineRx that, at the time of Delivery of the Merck Compound, such Merck Compound shall have been Manufactured and supplied in compliance with: (a) the Specifications for the Merck Compound; (b) the Clinical Quality Agreement; and (c) all Applicable Law, including cGMP and health, safety and environmental protections. Without limiting the foregoing, each Party is responsible for obtaining all regulatory approvals (including facility licenses) that are required to Manufacture its Compound in accordance with Applicable Law (provided that for clarity, BioLineRx shall be responsible for obtaining Regulatory Approvals for the Study as set forth in Section 3.4).

2.4 *Subcontracting*. Each Party shall have the right to subcontract any portion of its obligations hereunder: (i) to its own Affiliates, without the other Party's written consent; or (ii) to Third Parties; provided that the JDC has approved (in a written document) the use of such Third Parties in the performance of such activities prior to such Third Parties performing such activities; [*] (such Third Parties described above, "**Subcontractors**"). In any event, each Party shall remain solely and fully liable for the performance of its Affiliates and Subcontractors to which such Party delegates the performance of its obligations under this Agreement. Each Party shall ensure that each of its Affiliates and Subcontractors performs such Party's obligations pursuant to the terms of this Agreement, including the Appendices attached hereto. For clarity, to the extent that a Party has an obligation under this Agreement to perform an action or to meet a standard, and such Party subcontracts such obligation, such Party shall be responsible for any failure by such Party's Affiliates or Subcontractor to perform the action or meet the standard. Each Party shall use reasonable efforts to obtain and maintain copies of documents relating to the obligations performed by such Affiliates and Subcontractors that are required to be provided to the other Party under this Agreement.

2.5 *Compounds*. This Agreement does not create any obligation on the part of Merck to provide the Merck Compound for any activities other than the Study, nor does it create any obligation on the part of BioLineRx to provide the BioLineRx Compound for any activities other than the Study, except as expressly set forth in Section 3.14.

2.6 *Relationship*. Other than as expressly set forth in this Agreement, including Sections [*] and [*], or this Section 2.6, nothing in this Agreement shall (i) prohibit either Party from performing clinical studies other than the Study relating to its own Compound, either individually or in combination with any other compound or product, in any therapeutic area, or (ii) create an exclusive relationship between the Parties with respect to any Compound.

3 Conduct of the Study.

3.1 *Sponsor*. BioLineRx shall act as the sponsor of the Study under a new solid tumors IND for the BioLineRx Compound with a Right of Reference to the IND of the Merck Compound as further described in Section 3.4; provided, however, that in no event shall BioLineRx file an additional IND for the Study unless required by Regulatory Authorities to do so. If a Regulatory Authority requests an additional IND for the Study the Parties shall meet and mutually agree on an approach to address such requirement.

3.2 *Performance*. BioLineRx shall ensure that the Study is performed in accordance with this Agreement, the Protocol and all Applicable Law, including GCP. BioLineRx shall follow all applicable directions from applicable Regulatory Authorities, ethics committees and institutional review boards with jurisdiction over the Study, and shall obtain all applicable Regulatory Approvals required by applicable Regulatory Authorities, ethics committees and institutional review boards with jurisdiction over the Study prior to initiating performance of the Study.

3.3 *Debarred Personnel; Exclusion Lists*. A Party shall not employ or subcontract with any Person or Third Party that is excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs for the performance of the Study or any other activities under this Agreement or the Related Agreements. Each Party hereby certifies that it has not employed or otherwise used in any capacity and will not employ or otherwise use in any capacity, the services of any Person suspended, proposed for debarment, or debarred under United States law, including 21 USC 335a, or any foreign equivalent thereof, in performing any portion of the Study or other activities under this Agreement or the Related Agreements and that such Party has, as of the Effective Date, screened itself, and its officers and directors, against the Exclusions Lists and that it has informed the other Party in writing whether it or any of its officers or directors has been in Violation. A Party shall notify the other Party in writing immediately if any such suspension, proposed debarment, debarment or Violation occurs or comes to its attention, and shall, with respect to any Person so suspended, proposed for debarment, debarred or in Violation, promptly remove such Person from performing activities, function or capacity related to the Study or otherwise related to activities under this Agreement or the Related Agreements.

3.4 *Regulatory Matters*. BioLineRx shall ensure that all Regulatory Approvals from any Regulatory Authority, ethics committees and/or institutional review boards with jurisdiction over the Study are obtained prior to initiating performance of the Study. Merck shall have the right (but no obligation) to participate in any discussions with a Regulatory Authority regarding matters related to the Merck Compound. Each Party shall provide to the other, as necessary, a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate the Right of Reference. Notwithstanding anything to the contrary in this Agreement, neither Party shall have any right to access the other Party's CMC data with respect to its Compound. Merck shall authorize FDA and other applicable Regulatory Authorities to cross-reference the appropriate Merck Compound INDs and CTAs to provide data access to BioLineRx sufficient to support conduct of the Study. If Merck's CTA is not available in a given country, Merck will file its CMC data with the Regulatory Authority for such country, referencing BioLineRx's CTA as appropriate (however, BioLineRx shall have no right to directly access the CMC data).

3.5 *Documentation*. Each Party shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law. Each Party shall provide to the other Party Study information and documentation reasonably requested by the other Party to enable the other Party to (i) comply with any of its legal, regulatory and/or contractual obligations, or any request by any Regulatory Authority, related to the such other Party's Compound, and (ii) in the case of Merck, to determine whether the Study has been performed in accordance with this Agreement.

3.6 *Copies*. BioLineRx shall provide to Merck copies of all Clinical Data, in electronic form or other mutually agreeable alternate form and on the timelines specified in the Data Sharing and Sample Testing Schedule (if applicable) or upon mutually agreeable timelines [*]. BioLineRx shall ensure that all patient authorizations and consents required under HIPAA, the EU Data Protection Directive or any other similar Applicable Law in connection with the Study permit such sharing of Clinical Data with Merck.

3.7 *Samples*. BioLineRx shall provide Samples to Merck as specified in the Protocol or as agreed to by the Joint Development Committee. Each Party shall use the Samples only for the Sample Testing and each Party shall conduct the Sample Testing solely in accordance with the Data Sharing and Sample Testing Schedule (Schedule I) and the Protocol. Merck shall own all data arising from the Sample Testing conducted in accordance with this Section 3.7 by or on behalf of Merck, and such data shall be Merck's Confidential Information. Merck shall provide to BioLineRx the Sample Testing Results for such Sample Testing conducted by or on behalf of Merck, in electronic form or other mutually agreeable alternate form, and on the timelines specified in the Data Sharing and Sample Testing Schedule or other mutually agreed timelines. Likewise, BioLineRx shall own all data arising from the Sample Testing conducted in accordance with this Section 3.7 by or on behalf of BioLineRx, and such data shall be BioLineRx's Confidential Information. BioLineRx shall provide to Merck the Sample Testing Results for such Sample Testing conducted by or on behalf of BioLineRx, in electronic form or other mutually agreeable alternate form, and on the timelines specified in the Data Sharing and Sample Testing Schedule or other mutually agreed timelines. Except to the extent otherwise agreed in a writing signed by authorized representatives of each Party, each Party shall use the other Party's unpublished Sample Testing Results only for [*] (collectively, the "**Permitted Use**"). Any Sample Testing Results obtained by a Party which may have safety implications with respect to the Combination or a Compound will be immediately shared with the other Party. [*] If either Party chooses not to conduct or determines that it is unable to conduct one or more of the Sample tests set forth in Schedule I, the Parties shall consult with each other, and if there is no legal or Third Party contractual restriction on the other Party conducting such tests, the other Party shall have the right to conduct such tests, in which case the data from such Sample Testing shall be owned by such other Party and shall be deemed to be such Party's Confidential Information.

3.8 *Ownership and Use of Clinical Data*. All Clinical Data, including raw data and results, generated under this Agreement shall be jointly owned by BioLineRx and Merck. Merck hereby assigns to BioLineRx an undivided one-half interest in, to and under the Clinical Data. BioLineRx hereby assigns to Merck an undivided one-half interest in, to and under the Clinical Data. If such assignment cannot or does not occur, including in circumstances where such assignment is precluded by law, the Party with the obligation to assign hereby grants the other Party a non-exclusive license, with the right to grant sublicenses and to assign its license rights to the Clinical Data to any Person, in each case without the consent of the granting Party and without any accounting to such Party; provided that each such sublicensee and assignee is bound in writing to comply with the terms of this Agreement that are relevant to use and exploitation of such Clinical Data. BioLineRx shall maintain the Clinical Data in its internal database; provided, however, that at all times during the Term BioLineRx shall grant Merck access to all Clinical Data and any portions of BioLineRx's database that include Clinical Data. Notwithstanding the foregoing, and subject to the remaining provisions of this Section 3.8, [*] provided, however, that the foregoing shall not limit or restrict either Party's ability to use the Clinical Data as may be necessary to comply with Applicable Law or as may be necessary to comply with its internal policies and procedures with respect to pharmacovigilance and adverse event reporting. For the avoidance of doubt, BioLineRx shall be free to use/share (including publish) data and results from the Study, including Clinical Data, which are solely related to the single-agent use of the BioLineRx Compound and are not related to the Combination, and which have been generated during the treatment period in which the BioLineRx Compound is used in monotherapy. Neither Party shall disclose the Clinical Data to a Third Party except to the extent that such Clinical Data has been published as provided in Section 12.2 [*].

3.9 *Regulatory Submission*. It is understood and acknowledged by the Parties that positive Clinical Data could be used to obtain label changes for the Compounds. In such event, the Parties will enter into good faith negotiations to determine a regulatory submission strategy for the Compounds [*].

3.10 *Joint Development Committee*. The Parties shall form a joint development committee (the "**Joint Development Committee**" or "**JDC**"), made up of an equal number of representatives of Merck and BioLineRx, which shall have responsibility of coordinating all regulatory and other activities under, and pursuant to, this Agreement. Each Party shall designate a project manager (the "**Project Manager**") who shall be responsible for implementing and coordinating activities, and facilitating the exchange of information between the Parties, with respect to the Study. Other JDC members will be agreed by both Parties. The JDC shall meet as soon as practicable after the Effective Date and then no less than twice yearly, and more often as reasonably considered necessary at the request of either Party, to provide an update on the progress of the Study. The JDC may meet in person or by means of teleconference, Internet conference, videoconference or other similar communications equipment. Prior to any such meeting, the BioLineRx Project Manager shall provide an update in writing to the Merck Project Manager, which update shall contain information about the overall progress of the Study, recruitment status, interim analysis (if results available), final analysis and other information relevant to the conduct of the Study. In addition to a Project Manager, each Party shall designate an alliance manager (the "**Alliance Manager**"), who shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information, and shall serve as the primary point of contact for any issues arising under this Agreement. The Alliance Managers shall have the right to attend all JDC meetings and may bring to the attention of the JDC any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as the Parties may mutually agree in writing. In the event that an issue arises and the Alliance Managers cannot or do not, after good faith efforts, reach agreement on such issue, the issue shall be elevated to the Head of Clinical Oncology for Merck and the Vice President of Medical Affairs or Business Development for BioLineRx.

3.11 *Final Study Report*. BioLineRx shall provide Merck with (i) an electronic draft of the final Study report, for Merck to provide comments to BioLineRx within [*] days of receipt of the draft of the final Study report and (ii) a final version of the final Study report (the "**Final Study Report**") promptly following Study Completion. BioLineRx shall consider in good faith any comments provided by Merck on the draft of the final Study report and shall not include any statements relating to the Merck Compound [*]. "**Study Completion**" shall occur upon database lock of the Study results.

3.12 [*]

3.13 [*]

3.14 *Amendment to Agreement; Study Option*. Upon Study Completion (or at any earlier point agreed upon by the Parties), either Party shall have the option to propose amending this Agreement and the Related Agreements for the purpose of including a Phase III registration study for the Combination [*]

4 Protocol and Related Documents.

4.1 *Protocol*. A summary of the initial Protocol will be finalized and agreed upon by the Parties within [*] days after the Effective Date, using the most recent draft discussed between the Parties attached hereto as Appendix A. BioLineRx shall provide a draft of the Protocol (and any subsequent revisions thereof) to Merck for Merck's review and comment, consistent with the remaining provisions of this Section 4.1.

4.1.1 Notwithstanding the provisions of Section 4.1, each Party shall have the following decision rights:

a) BioLineRx shall have the final decision-making authority with respect to the contents of the Protocol, provided that any material changes to any draft of the Protocol (other than relating solely to the BioLineRx Compound) from the draft of the Protocol previously provided to Merck, any material changes (other than relating solely to the BioLineRx Compound) to the approved final Protocol, and [*], shall require Merck's prior written consent. Any such proposed changes will be sent in writing to Merck's Project Manager and Merck's Alliance Manager. Merck will provide such consent, or a written explanation for why such consent is being withheld, within [*] Business Days of receiving a copy of BioLineRx's requested changes.

b) [*]

c) [*]

4.2 *Informed Consent*. BioLineRx shall prepare the patient informed consent form for the Study (which shall include provisions regarding the use of Samples in Sample Testing) in consultation with Merck (it being understood and agreed that the portion of the informed consent form relating to the Sample Testing of the Merck Compound shall be provided to BioLineRx by Merck). Any proposed changes to such form that relate to the Merck Compound, including Sample Testing of the Merck Compound, shall be subject to Merck's review and written consent. Any such proposed changes will be sent in writing to Merck's Project Manager and Merck's Alliance Manager. Merck will provide such consent, or a written explanation for why such consent is being withheld, within [*] Business Days of receiving a copy of BioLineRx's requested changes.

5 Adverse Event Reporting.

5.1 BioLineRx will be solely responsible for compliance with all Applicable Law pertaining to safety reporting for the Study and related activities. The Parties will use their reasonable efforts to execute a pharmacovigilance agreement ("**Pharmacovigilance Agreement**") within [*] days of the Effective Date, and in any event prior to the initiation of clinical activities under the Study to ensure the exchange of relevant safety data within appropriate timeframes and in an appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. The Pharmacovigilance Agreement will include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the Merck Compound and BioLineRx Compound in the Study, consistent with Applicable Law. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to Government Authorities. BioLineRx will transmit to Merck serious adverse drug reactions ("**SADRs**") and serious adverse events ("**SAEs**") as follows:

5.1.1 For fatal and life-threatening SADRs, BioLineRx will send an early case notification to Merck within [*], followed by a completely processed case (on a CIOMS-1 form) within [*].

5.1.2 For all other SAEs, BioLineRx will send an early case notification to Merck within [*] followed by a completely processed case (on a CIOMS-1 form) within [*].

The early case notification will be marked as "Notification" and will contain the minimum criteria including an identifiable reporter, an identifiable patient, event term, and suspect therapy.

6 Term and Termination.

6.1 *Term*. The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until the earlier of (i) delivery of the Final Study Report and (ii) Study Completion plus three (3) months, or until terminated by either Party pursuant to this Article 6 (the "**Term**").

6.2 *Merck Termination Right for Safety or for OCS Non-Consent*. Merck shall have the unilateral right to terminate this Agreement pursuant to Section 10.1.1. Additionally, in the event that Merck in good faith believes that the Merck Compound is being used in the Study in an unsafe manner and notifies BioLineRx in writing of the grounds for such belief, and if after receipt of such written notice, BioLineRx fails to promptly incorporate changes into the Protocol that are requested by Merck in writing to address such notified issue or to otherwise reasonably and in good faith address such notified issue, then Merck may immediately terminate this Agreement and the supply of the Merck Compound upon five (5) Business Days' prior written notice to BioLineRx. During such five (5) Business Days period, BioLineRx shall have the right and opportunity to demonstrate that responsive Protocol changes have been incorporated.

6.3 *Material Breach*. Either Party may terminate this Agreement if the other Party commits a material breach of this Agreement, and such material breach continues for thirty (30) days after receipt of written notice thereof from the non-breaching Party describing such breach and demanding its cure; provided that if such material breach cannot reasonably be cured within thirty (30) days, the breaching Party shall be given a reasonable period of time to cure such breach; provided further, that if such material breach is incapable of cure, then the notifying Party shall state such belief in its written breach notice, and if the breaching Party does not dispute such belief, the non-breaching Party may terminate this Agreement effective after the expiration of such thirty (30) day period.

6.4 *Mutual Termination Right for Patient Safety*. If either Party determines in good faith, based on a review of the Clinical Data, Sample Testing Results or other Study-related Know-How or other information, that the Study may unreasonably affect patient safety, such Party shall promptly notify the other Party of such determination in writing. The Party receiving such notice may propose modifications to the Study to address the safety issue identified by the other Party and, if the notifying Party agrees, shall act to immediately implement such modifications; provided, however, that if the notifying Party, in its sole discretion, believes that there is imminent danger to patients, such Party need not wait for the other Party to propose modifications and may instead suspend the Study immediately upon written notice to such other Party. Furthermore, if the notifying Party, in its sole discretion, believes that any modifications proposed by the other Party will not resolve the patient safety issue, such Party may terminate this Agreement effective upon written notice to such other Party.

6.5 *Mutual Termination Right Due to Regulatory Action; Other Reasons*. Either Party may terminate this Agreement upon five (5) Business Days' prior written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that prevents the terminating Party from any further supply of its Compound for purposes of the Study. Additionally, either Party shall have the right to terminate this Agreement upon five (5) Business Days' prior written notice to the other Party in the event that it determines in its sole discretion to withdraw any applicable Regulatory Approval for its Compound or to discontinue development of its Compound, for medical, scientific or legal reasons.

6.6 *[Deleted]*

6.7 *Return of Merck Compound*. In the event that this Agreement is terminated, or in the event BioLineRx remains in possession (including through any Affiliate or Subcontractor) of Merck Compound at the time this Agreement expires, BioLineRx shall, at Merck's sole discretion, promptly either return or destroy all unused Merck Compound pursuant to Merck's instructions. If Merck requests that BioLineRx destroy the unused Merck Compound, BioLineRx shall provide written certification of such destruction. Notwithstanding anything to the contrary in the foregoing, if this Agreement is terminated (a) due to patient safety or regulatory issues, the Parties will share the costs incurred by BioLineRx for such return or destruction of the Merck Compound, or (b) due to an uncured material breach by a breaching Party, then the breaching Party shall be solely responsible for the costs incurred by BioLineRx for such return or destruction of the Merck Compound.

6.8 *Anti-Corruption*. Either Party shall have the right to terminate this Agreement immediately upon written notice to the other Party, if such other Party fails to perform any of its obligations under Section 13.4 or breaches any representation or warranty contained in Section 13.4. The non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 6.8.

6.9 *Survival*. The provisions of this Section 6.9 and Sections 3.4 through 3.9 (inclusive), 5.1, 6.6, 8.11, 12.2, 14.2, 14.3, and Articles 1, 9, 10, 11, 20, 21, 23, 24, 25 and 26 shall survive the expiration or termination of this Agreement.

6.10 *No Prejudice*. Termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach of this Agreement.

6.11 *Confidential Information*. Upon termination of this Agreement, each Party and its Affiliates shall promptly return to the Disclosing Party or destroy any Confidential Information of the Disclosing Party (other than Clinical Data, Sample Testing Results and Inventions, which may be used in accordance with this Agreement) furnished to the Receiving Party by the Disclosing Party, except that the Receiving Party shall have the right to retain one copy for record-keeping purposes. For clarity, any data or information (including Clinical Data) disclosed to a Receiving Party that relates to the single-agent use of the other Party's Compound shall be promptly returned to the other Party or destroyed in accordance with this Section 6.11.

6.12 *Merck's Manufacturing Costs*. Provided the Parties do not otherwise dispute the circumstances of termination, in the event of termination by Merck pursuant to Section 6.2 or 6.3 above, Merck shall be entitled to reimbursement by BioLineRx for the Direct Manufacturing Costs and Indirect Manufacturing Costs (as defined herein) incurred by Merck for its Compound Delivered for the Study. "**Direct Manufacturing Costs**" shall be calculated consistent with Generally Accepted Accounting Principles ("**GAAP**") and include manufacturing fees; raw materials; direct labor; freight and duty, and factory overhead costs that can be directly attributed to the Compound, including but not limited to equipment maintenance and repair, supplies, ongoing stability program costs, other plant services, indirect labor and depreciation on direct capital assets. "**Indirect Manufacturing Costs**" shall be calculated consistent with GAAP and include allocations of indirect factory overhead and site support costs, including but not limited to utilities, quality, planning, engineering, maintenance, safety, site science and technology, and depreciation on indirect capital assets, procurement, warehousing, and corporate services. Allocations shall be based on each compound's utilization relative to a manufacturing site's total activity.

6.13 *BioLineRx's Study Costs; Unused Samples*. Provided the Parties do not otherwise dispute the circumstances of termination, in the event of termination by BioLine pursuant to Section 6.3 above, BioLineRx shall be entitled to (a) reimbursement by Merck for the cost of replacing Merck Compound in the Study; and (b) require Merck to destroy or, at Merck's discretion, return to BioLineRx any unused Samples provided by BioLineRx to Merck.

7 Costs of Study.

The Parties agree that (i) Merck shall provide the Merck Compound for use in the Study, as described in Article 8 below; (ii) each Party will be responsible for its own internal costs and expenses to support the Study and the costs of any Sample Testing conducted by such Party in connection with the Study, and (iii) BioLineRx shall bear all other costs associated with the conduct of the Study, including that BioLineRx shall provide the BioLineRx Compound for use in the Study, as described in Article 8 below. For the avoidance of doubt, BioLineRx will not be required to reimburse Merck for any costs or expenses incurred by Merck or its Affiliates in connection with the Study and Merck will not be required to reimburse BioLineRx for any costs or expenses incurred by BioLineRx or its Affiliates in connection with the Study.

8 Supply and Use of the Compounds.

8.1 *Supply of the Compounds*. Subject to the terms and conditions of this Agreement, BioLineRx and Merck will each use commercially reasonable efforts to supply, or cause to be supplied, such quantities of its Compound in accordance with the delivery schedule to be agreed-upon in writing within [*] calendar days after the Effective Date, which delivery schedule upon such written agreement shall be incorporated herein as Appendix B. In the event that BioLineRx determines that the quantities of Compounds as set forth on the delivery schedule determined in accordance with this Section 8.1 are not sufficient to complete the Study, BioLineRx shall so notify Merck in writing, and the Parties shall discuss in good faith regarding whether additional quantities of Compounds may be provided and the schedule on which such additional quantities may be provided. Each Party shall also provide to the other Party a contact person for the supply of its Compound under this Agreement. [*]

8.2 *Clinical Quality Agreement*. Within [*] days from the Effective Date of this Agreement, the Parties shall enter into a quality agreement that shall address and govern issues related to the quality of clinical Compounds to be supplied by the Parties for use in the Study ("**Clinical Quality Agreement**"). The Clinical Quality Agreement shall, among other things: (i) detail classification of any Compound found to have a Non-Conformance; (ii) include criteria for Manufacturer's Release and related certificates and documentation; (iii) include criteria and timeframes for acceptance of Merck Compound; (iv) include procedures for the resolution of disputes regarding any Compounds found to have a Non-Conformance; and (v) include provisions governing the recall of Compounds.

8.3 *Minimum Shelf Life Requirements*. Each Party shall use diligent and commercially reasonable efforts to supply its Compound hereunder with an adequate remaining shelf life at the time of Delivery to meet the Study requirements.

8.4 *Provision of Compounds.*

8.4.1 Subject to Section 10.1.1, Merck will deliver the Merck Compound [*] to BioLineRx's, or its designee's, location as specified by BioLineRx ("**Delivery**" with respect to such Merck Compound). Title and risk of loss for the Merck Compound shall transfer from Merck to BioLineRx at Delivery. All costs associated with the subsequent transportation, warehousing and distribution of Merck Compound shall be borne by [*]. BioLineRx will, or will cause its designee to: (i) take delivery of the Merck Compound supplied hereunder; (ii) perform the acceptance procedures allocated to it under the Clinical Quality Agreement; (iii) subsequently label and pack the Merck Compound (in accordance with Section 8.5), and promptly ship the Merck Compound to the Study sites for use in the Study, in compliance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement; and (iv) provide, from time to time at the reasonable request of Merck, the following information: any applicable chain of custody forms, in-transport temperature recorder(s), records and receipt verification documentation, such other transport or storage documentation as may be reasonably requested by Merck, and usage and inventory reconciliation documentation related to the Merck Compound.

8.4.2 BioLineRx is solely responsible, at its own cost, for supplying (including all Manufacturing, acceptance and release testing) the BioLineRx Compound for the Study, and the subsequent handling, storage, transportation, warehousing and distribution of the BioLineRx Compound supplied hereunder for the Study. BioLineRx shall ensure that all such activities are conducted in compliance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement. For purposes of this Agreement, the "**Delivery**" of a given quantity of the BioLineRx Compound shall be deemed to occur when such quantity is packaged for shipment to a Study site.

8.5 *Labeling and Packaging; Use, Handling and Storage.*

8.5.1 The Parties' obligations with respect to the labeling and packaging of the Compounds are as set forth in the Clinical Quality Agreement. Notwithstanding the foregoing or anything to the contrary contained herein, Merck shall provide the Merck Compound to BioLineRx in the form of unlabeled vials, and BioLineRx shall be responsible for labeling, packaging and leafleting such Merck Compound in accordance with the terms and conditions of the Clinical Quality Agreement and otherwise in accordance with all Applicable Law, including cGMP, GCP, and health, safety and environmental protections.

8.5.2 BioLineRx shall (i) use the Merck Compound solely for purposes of performing the Study; (ii) not use the Merck Compound in any manner that is inconsistent with this Agreement or for any commercial purpose; and (iii) label, use, store, transport, handle and dispose of the Merck Compound in compliance with Applicable Law and the Clinical Quality Agreement, as well as all written instructions of Merck. BioLineRx shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the Merck Compound, and in particular shall not analyze the Merck Compound by physical, chemical or biochemical means, except as necessary to perform its obligations under the Clinical Quality Agreement.

8.6 *Product Specifications*. A certificate of analysis prepared and delivered in accordance with the Clinical Quality Agreement shall accompany each shipment of the Merck Compound to BioLineRx. Upon request, BioLineRx shall provide Merck with a certificate of analysis covering each shipment of BioLineRx Compound used in the Study.

8.7 *Changes to Manufacturing*. Each Party may make changes from time to time to its Compound or the Manufacturing Site; provided that such changes shall be in accordance with the Clinical Quality Agreement.

8.8 *Product Testing; Noncompliance*.

8.8.1 *After Manufacturer's Release.* After Manufacturer's Release of the Merck Compound and concurrently with Delivery of the Compound to BioLineRx, Merck shall provide BioLineRx with such certificates and documentation as are described in the Clinical Quality Agreement ("**Disposition Package**"). BioLineRx shall, within the time defined in the Clinical Quality Agreement, perform (i) with respect to the Merck Compound, the acceptance (including testing) procedures allocated to it under the Clinical Quality Agreement, and (ii) with respect to the BioLineRx Compound, the testing and release procedures allocated to it under the Clinical Quality Agreement. BioLineRx shall be solely responsible for taking all steps necessary to determine that Merck Compound or BioLineRx Compound, as applicable, is suitable for release before making such Merck Compound or BioLineRx Compound, as applicable, available for human use, and Merck shall provide cooperation or assistance as reasonably requested by BioLineRx in connection with such determination with respect to the Merck Compound. BioLineRx shall be responsible for storage and maintenance of the Merck Compound until it is tested and/or released, which storage and maintenance shall be in compliance with (a) the Specifications for the Merck Compound, the Clinical Quality Agreement and Applicable Law, and (b) any specific storage and maintenance requirements as may be provided by Merck from time to time. BioLineRx shall be responsible for any failure of the Merck Compound to meet the Specifications to the extent caused by shipping, storage or handling conditions after Delivery to BioLineRx hereunder.

8.8.2 *Non-Conformance.*

a) In the event that either Party becomes aware that any Compound may have a Non-Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Section 8.8.1), such Party shall immediately notify the other Party in accordance with the procedures of the Clinical Quality Agreement. The Parties shall investigate any Non-Conformance in accordance with Section 8.9 (*Investigations*) and any discrepancy between them shall be resolved in accordance with Section 8.8.3.

b) In the event that any proposed or actual shipment of the Merck Compound (or portion thereof) shall be agreed to have a Non-Conformance at the time of Delivery to BioLineRx, then unless otherwise agreed to by the Parties in writing, Merck shall replace such Merck Compound as is found to have a Non-Conformance (with respect to Merck Compound that has not yet been administered in the course of performing the Study) within [*] calendar days, at Merck's sole expense. [*]

c) BioLineRx shall be responsible for, and Merck shall have no obligations or liability with respect to, any BioLineRx Compound supplied hereunder that is found to have a Non-Conformance. BioLineRx shall replace any BioLineRx Compound for use in the Study as is found to have a Non-Conformance (with respect to BioLineRx Compound that has not yet been administered in the course of performing the Study).

8.8.3 *Resolution of Discrepancies*. Disagreements regarding any determination of Non-Conformance by BioLineRx shall be resolved in accordance with the provisions of the Clinical Quality Agreement.

8.9 *Investigations*. The process for investigations of any Non-Conformance shall be handled in accordance with the Clinical Quality Agreement.

8.10 *Shortage; Allocation*. In the event that a Party's Compound is in short supply as a result of a manufacturing disruption, manufacturing difficulties or other similar event such that a Party reasonably believes in good faith that it will not be able to fulfill its entire supply obligations hereunder with respect to its Compound, such Party will provide prompt written notice to the other Party thereof (including the shipments of Compound hereunder expected to be impacted and the quantity of its Compound that such Party reasonably determines it will be able to supply) and the Parties will promptly discuss such situation (including how the quantity of Compound that such Party is able to supply hereunder will be allocated within the Study). In such event, the Party experiencing such shortage shall (i) use its diligent and commercially reasonable efforts to remedy the situation giving rise to such shortage and to take action to minimize the impact of the shortage on the Study, and (ii) allocate to the other Party [*]

8.11 *Records; Audit Rights*. During the Term of this Agreement and [*] years after the end of the Term, BioLineRx shall keep complete and accurate records pertaining to its use and disposition of Merck Compound (including its storage, shipping (cold chain) and chain of custody activities) and, upon written request of Merck, shall make such records open to review by Merck solely for the purpose of conducting investigations for the determination of Merck Compound safety and/or efficacy and BioLineRx's compliance with this Agreement with respect to the Merck Compound.

8.12 *Quality*. Quality matters related to the Manufacture of the Compounds shall be governed by the terms of the Clinical Quality Agreement in addition to the relevant quality provisions of this Agreement.

8.13 *Quality Control*. Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Compound, and for validation, documentation and release of its Compound and such other quality assurance and quality control procedures as are required by the Specifications, cGMPs and the Clinical Quality Agreement.

8.14 *Audits and Inspections*. The Parties' audit and inspection rights related to this Agreement shall be governed by the terms of the Clinical Quality Agreement.

8.15 *Recalls*. Recalls of the Compounds shall be governed by the terms of the Clinical Quality Agreement.

8.16 *VAT*. It is understood and agreed between the Parties that any payments made under this Agreement are exclusive of any value added or similar tax ("**VAT**"), which shall be added thereon as applicable. Where VAT is properly charged by the supplying Party and added to a payment made under this Agreement, the Party making the payment will pay the amount of VAT only on receipt of a valid tax invoice from the supplying Party issued in accordance with the laws and regulations of the country in which the VAT is chargeable.

9 Confidentiality.

9.1 *Confidential Information*. Subject to Section 13.4.8, BioLineRx and Merck agree to hold in confidence any Confidential Information provided by the other Party, and neither Party shall use Confidential Information of the other Party except for the performance of the Study and for the Permitted Use. The Receiving Party shall not, without the prior written permission of the Disclosing Party, disclose any Confidential Information of the Disclosing Party to any Third Party except to the extent disclosure (i) is required by Applicable Law; (ii) is pursuant to and in accordance with the terms of this Agreement; or (iii) is necessary for the conduct of the Study, and in each case ((i) through (iii)) provided that the Receiving Party shall provide reasonable advance written notice to the Disclosing Party before making such disclosure. For the avoidance of doubt, BioLineRx may, without Merck's consent, disclose Merck's Confidential Information to clinical trial sites and clinical trial investigators performing the Study, the data safety monitoring and advisory board relating to the Study, and Regulatory Authorities working with BioLineRx on the Study, in each case to the extent necessary for the performance of the Study and provided that such Persons (other than governmental entities) are bound by an obligation of confidentiality at least as stringent as the obligations contained herein.

9.2 *Inventions*. Notwithstanding the foregoing, (i) Inventions that constitute Confidential Information and are jointly owned by the Parties, shall constitute the Confidential Information of both Parties and each Party shall have the right to use and disclose such Confidential Information consistent with Articles 10, 11 and 12 and (ii) Inventions that constitute Confidential Information and are solely owned by one Party shall constitute the Confidential Information of that Party and each Party shall have the right to use and disclose such Confidential Information consistent with Articles 10, 11 and 12.

9.3 *Personal Identifiable Data*. All Confidential Information containing personal identifiable data shall be handled in accordance with all data protection and privacy laws, rules and regulations applicable to such data.

10 Intellectual Property.

10.1 *Joint Ownership and Prosecution*.

10.1.1 Subject to Section 10.2 and Section 10.3, all rights to all Inventions relating to, or covering, [*] (each a "**Jointly Owned Invention**") shall be negotiated in good faith in an additional agreement setting forth the rights of the Parties with respect to such Jointly Owned Invention (the "**Joint Rights Agreement**"), which Joint Rights Agreement shall be executed within [*] days after the Effective Date, and shall contain the provisions set forth in Sections 10.1.2 and 10.1.3 of this Agreement. The Parties acknowledge that the Office of the Chief Scientist of the Ministry of Economy of the State of Israel (the "**OCS**") must consent to the Joint Rights Agreement before such Agreement becomes effective. Promptly after the Effective Date, BioLineRx shall use its best efforts to obtain the consent of the OCS to the Joint Rights Agreement, having the terms set forth in Sections 10.1.2 and 10.1.3 below, and shall use its best efforts to seek to obtain such consent no later than [*] after the Effective Date. BioLineRx shall be solely responsible for all costs and fees, or other compensation to the OCS or any other Third Party, required to secure such rights. The parties acknowledge that there is a possibility that the OCS may request changes in this Agreement and the Joint Rights Agreement as a result of its review of the Joint Rights Agreement. In such event, the Parties shall negotiate in good faith to agree on amendments to either or both of such agreements in accordance with the OCS request. [*]

10.1.2 Subject to any changes that may be required in order to obtain the consent of the OCS to the Joint Rights Agreement as set forth in Section 10.1.1, such agreement will contain the following terms:

a. For Jointly Owned Inventions that are invented or created jointly by Merck or by Persons having an obligation to assign such rights to Merck, and by BioLineRx or by Persons having an obligation to assign such rights to BioLineRx, each Party shall have an undivided one-half interest in, to and under any such Jointly Owned Inventions. [*]

b. [*]

c. [*]

d. If one Party brings any prosecution or enforcement action or proceeding against a Third Party with respect to any Joint Patent, the second Party agrees to be joined as a party plaintiff where necessary and to give the first Party reasonable assistance and authority to file and prosecute the suit. The costs and expenses of the (first) Party bringing suit under this subsection (d) shall be borne by such Party, and any damages or other monetary awards recovered shall be shared as follows: [*]A settlement or consent judgment or other voluntary final disposition of a suit under this subsection (d) may not be entered into without the consent of the Party not bringing or controlling the suit.

10.1.3 Promptly following the receipt of the consent of OCS to the Joint Rights Agreement, patent representatives of each of the Parties shall meet (in person or by telephone) to discuss the patenting strategy for any Jointly Owned Inventions which may arise. In particular, the Parties shall discuss which Party will file a patent application (including any provisional, substitution, divisional, continuation, continuation in part, reissue, renewal, reexamination, extension, supplementary protection certificate and the like) in respect of any Jointly Owned Invention (each, a "**Joint Patent Application**") and whether the Parties wish to appoint joint patent counsel. In any event, the Parties shall consult and reasonably cooperate with one another in the preparation, filing, prosecution (including prosecution strategy) and maintenance of such each Joint Patent Application and shall [*]. In the event that one Party (the "**Filing Party**") wishes to file a patent application for a Jointly Owned Invention and the other Party (the "**Non-Filing Party**") does not want to file a patent application for such Jointly Owned Invention or does not want to file in a particular country, the Non-Filing Party shall execute such documents and perform such acts at the Filing Party's reasonable expense as may be reasonably necessary to effect an assignment of such Jointly Owned Invention to the Filing Party (in such country or all countries, as applicable) in a timely manner to allow the Filing Party to file and prosecute such patent application. Likewise, if a Party (the "**Opting-out Party**") wishes to discontinue the prosecution and maintenance (or sharing in the costs with respect thereto) of a Joint Patent Application (in one or more countries), the other Party, at its sole option (the "**Continuing Party**"), may continue such prosecution and maintenance. In such event, the Opting-out Party shall execute such documents and perform such acts at the Continuing Party's [*] to effect an assignment of such Joint Patent Application to the Continuing Party (in such country or all countries, as applicable) in a timely manner to allow the Continuing Party to prosecute and maintain such patent application. [*]

10.1.4 Except as expressly provided in Section 10.1.3 and in furtherance and not in limitation of Section 9.1, each Party shall not file a patent application based on the other Party's Confidential Information, and shall give no assistance to any Third Party for such application, without the other Party's prior written authorization.

10.2 *Inventions Owned by BioLineRx*. Notwithstanding Section 10.1, the Parties agree that all rights to Inventions relating [*], are the exclusive property of BioLineRx ("**BioLineRx Inventions**"). BioLineRx shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any BioLineRx Invention. [*]

10.3 *Inventions Owned by Merck*. Notwithstanding Section 10.1, the Parties agree that all rights to Inventions relating [*], are the exclusive property of Merck ("**Merck Inventions**"). Merck shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any Merck Invention. [*]

10.4 [deleted]

11 Reprints; Rights of Cross-Reference.

Consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences and/or symposia relating to the Study which disclose the name of a Party, provided such use does not constitute an endorsement of any commercial product or service by the other Party.

12 Publications; Press Releases.

12.1 *Clinical Trial Registry*. BioLineRx shall register the Study with the Clinical Trials Registry located at www.clinicaltrials.gov and is committed to timely publication of the results following Study Completion, after taking appropriate action to secure intellectual property rights (if any) arising from the Study. The publication of the results of the Study will be in accordance with the Protocol.

12.2 *Publication*. BioLineRx, as sponsor of the Study, shall have the first right to publish the results of the Study. Upon Study completion or termination (as applicable), or earlier if mutually agreed by the Parties, and after BioLineRx has an opportunity for first publication of the Study results, each Party shall use reasonable efforts to publish or present scientific papers dealing with the Study in accordance with accepted scientific practice. The Parties agree that prior to submission of the results of the Study for publication or presentation or any other dissemination of results including oral dissemination, the publishing Party shall invite the other Party to comment on the content to be published or presented according to the following procedure:

12.2.1 At least [*] days prior to submission for publication of any paper, letter or any other publication, or [*] days prior to submission for presentation of any abstract, poster, talk or any other public presentation, the publishing Party shall provide to the other Party the full details of the proposed publication or presentation in an electronic version (cd-rom or email attachment). Upon written request from the other Party, the publishing Party will not submit data for publication/presentation for an additional [*] days in order to allow for actions to be taken to preserve rights for patent protection.

12.2.2 The publishing Party shall give reasonable consideration to any request by the other Party made within the periods mentioned in Section 12.2.1 to modify the publication and the Parties shall work in good faith and in a timely manner to resolve any issue regarding the content for publication.

12.2.3 The publishing Party shall remove all Confidential Information of the other Party before finalizing the publication.

12.2.4 For clarity, nothing in this Section 12.2 restricts in any way the right of a Party to publish data or results relating to single agent use of its Compound.

12.3 *Press Releases*. On or immediately following the Effective Date, the Parties will issue a press release in the form attached hereto as Appendix C. [*] Each Party agrees to identify the other Party and acknowledge such other Party's support of the Study in any press release and any other publication or presentation concerning the Study. [*] For clarity, nothing in this Section 12.3 restricts in any way the right of a Party to publish data or results relating to single agent use of its Compound.

13 Representations and Warranties; Disclaimers.

13.1 [*]

13.2 *Compounds*.

13.2.1 BioLineRx Compound. BioLineRx hereby represents and warrants to Merck that (i) BioLineRx has the full right, power and authority to grant all of the licenses granted to Merck under this Agreement, and (ii) BioLineRx Controls the BioLineRx Compound.

13.2.2 Merck Compound. Merck hereby represents and warrants to BioLineRx that (i) Merck has the full right, power and authority to grant all of the licenses granted to BioLineRx under this Agreement, and (ii) Merck Controls the Merck Compound.

13.3 *Results*. BioLineRx does not undertake that the Study shall lead to any particular result, nor is the success of the Study guaranteed. Merck does not undertake that the Study shall lead to any particular result, nor is the success of the Study guaranteed. Neither Party shall be liable for any use that the other Party may make of the Clinical Data nor for advice or information given in connection therewith.

13.4 *Anti-Corruption*

13.4.1 In performing their respective obligations hereunder, the Parties acknowledge that the corporate policies of BioLineRx and Merck and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the business contemplated herein in a manner which is consistent with all Applicable Law, including the Stark Act, Anti-Kickback Statute, Sunshine Act, and the U.S. Foreign Corrupt Practices Act, good business ethics, and its ethics and other corporate policies and agrees to abide by the spirit of the other Party's guidelines for performance in accordance with its corporate policies, which may be provided by such other Party from time to time.

13.4.2 Specifically, each Party represents and warrants that it has not, and covenants that it, its Affiliates, and its and its Affiliates' directors, employees, officers, and anyone acting on its behalf, will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it in obtaining or retaining business for it or the other Party, or in any way with the purpose or effect of public or commercial bribery.

13.4.3 Each Party shall not contact, or otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.

13.4.4 Each Party represents and warrants that it (i) is not excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs; and (ii) has not employed or subcontracted with any Person or Third Party for the performance of the Study who is excluded, debarred, suspended, proposed for suspension or debarment, or is in Violation or otherwise ineligible for government programs.

13.4.5 Each Party represents and warrants that except as disclosed to the other Party in writing prior to the Effective Date: (1) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; (2) it shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of the other Party in performance of this Agreement; and (3) it has provided complete and accurate information and documentation to the other Party, the other Party's Affiliates and its and their personnel in the course of due diligence conducted by the other Party for this Agreement, including disclosure of any officers, employees, owners or Persons directly or indirectly retained by such Party in relation to the performance of this Agreement who are Government Officials or relatives of Government Officials. Each Party shall make all further disclosures as necessary to the other Party to ensure the information provided remains complete and accurate throughout the Term. Subject to the foregoing, each Party agrees that it shall not hire or retain any Government Official to assist in its performance of this Agreement, with the sole exception of conduct of or participation in clinical trials under this Agreement, provided that such hiring or retention shall be subject to the completion by the hiring or retaining Party of a satisfactory anti-corruption and bribery (*e.g.*, FCPA) due diligence review of such Government Official. Each Party further covenants that any future information and documentation submitted to the other Party as part of further due diligence or a certification shall be complete and accurate.

13.4.6 Each Party shall have the right during the Term, and for a period of two (2) years following termination of this Agreement, to conduct an investigation and audit of the other Party's activities, books and records, to the extent they relate to that other Party's performance under this Agreement, solely to verify compliance with the terms of this Section 13.4. Such other Party shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of the Party requesting such audit, but also reasonably acceptable to the audited Party.

13.4.7 Each Party shall use commercially reasonable efforts to ensure that all transactions under this Agreement are properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects. Each Party further represents, warrants and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of transactions and expenditures. Each Party shall maintain a system of internal accounting controls reasonably designed to ensure that no off-the-books or similar funds or accounts will be maintained or used in connection with this Agreement.

13.4.8 Each Party agrees that in the event that the other Party believes in good faith that there has been a possible violation of any provision of Section 13.4, such other Party may make full disclosure of such belief and related information needed to support such belief at any time and for any reason to any competent government bodies and its agencies, and to whoever such Party determines in good faith has a legitimate need to know; provided, however, that the Party wishing to make the disclosure shall give the other Party at least five (5) days' written notice of such intention.

13.4.9 Each Party shall comply with its own ethical business practices policy and any corporate integrity agreement (if applicable) to which it is subject, and shall conduct its Study-related activities in accordance with Applicable Law. Each Party shall ensure that all of its employees involved in performing its obligations under this Agreement are made specifically aware of the compliance requirements under this Section 13.4. In addition, each Party shall ensure that all such employees participate in and complete mandatory compliance training to be conducted by each Party, including specific training on anti-bribery and corruption, prior to his/her performance of any obligations or activities under this Agreement. Each Party further shall certify its continuing compliance with the requirements under this Section 13.4 on a periodic basis during the Term in such form as may be reasonably specified by the other Party.

13.4.10 Each Party shall have the right to terminate this Agreement immediately upon the other Party's violation of this Section 13.4 in accordance with Section 6.8, provided that the other Party has been provided with written notice of the reasons for termination and has had an opportunity to promptly respond to such reasons.

13.5 *DISCLAIMER*. EXCEPT AS EXPRESSLY PROVIDED HEREIN, MERCK MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE MERCK COMPOUND, AND BIOLINERX MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE BIOLINERX COMPOUND.

14 Insurance; Indemnification; Limitation of Liability.

14.1 *Insurance*. Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon written request, a Party shall provide evidence of such insurance.

14.2 *Indemnification*.

14.2.1 Indemnification by BioLineRx. BioLineRx agrees to defend, indemnify and hold harmless Merck, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any loss, damage, reasonable costs and expenses (including reasonable attorneys' fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out [*] (a "**Liability**"), to the extent such Liability [*].

14.2.2 Indemnification by Merck. Merck agrees to defend, indemnify and hold harmless BioLineRx, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any Liability to the extent such Liability [*].

14.2.3 Procedure. The obligations of Merck and BioLineRx under this Section 14.2 are conditioned upon the delivery of written notice to Merck or BioLineRx, as the case might be, of any potential Liability within the other Party's indemnification obligation, within a reasonable time after such Party becomes aware of such potential Liability. The indemnifying Party will have the right to assume the defense of any suit or claim related to the Liability (using counsel reasonably satisfactory to the indemnified Party) if it has assumed responsibility for the suit or claim in writing; provided that the indemnified Party may assume the responsibility for such defense to the extent the indemnifying Party does not do so in a timely manner. The indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The Party controlling such defense (the "**Defending Party**") shall keep the other Party (the "**Other Party**") advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the Other Party with respect thereto. The Defending Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Other Party, which shall not be unreasonably withheld, conditioned or delayed. The Defending Party, but solely to the extent the Defending Party is also the indemnifying Party, shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Other Party from all liability with respect thereto or that imposes any liability or obligation on the Other Party without the prior written consent of the Other Party.

14.2.4 Study Subjects. BioLineRx shall not offer compensation on behalf of Merck to any Study subject or bind Merck to any indemnification obligations in favor of any Study subject. Likewise, Merck shall not offer compensation on behalf of BioLineRx to any Study subject or bind BioLineRx to any indemnification obligations in favor of any Study subject.

14.3 *LIMITATION OF LIABILITY*. IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY FOR, NOR SHALL ANY INDEMNIFIED PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS OR DAMAGES FOR LOST OPPORTUNITIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (X) THE MANUFACTURE OR USE OF ANY COMPOUND SUPPLIED HEREUNDER OR (Y) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR ANY REPRESENTATION, WARRANTY OR COVENANT CONTAINED IN OR MADE PURSUANT TO THIS AGREEMENT, EXCEPT THAT SUCH LIMITATION SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFYING PARTY FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION HEREUNDER OR WITH RESPECT TO DAMAGES ARISING OUT OF OR RELATED TO A PARTY'S BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT TO USE, DISCLOSE, LICENSE, ASSIGN OR OTHERWISE TRANSFER CLINICAL DATA, CONFIDENTIAL INFORMATION, JOINTLY-OWNED INVENTIONS AND SAMPLE TESTING RESULTS ONLY FOR THE PERMITTED USE.

15 Use of Name.

Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement without the other Party's prior written consent.

16 Force Majeure.

If, in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (*e.g.*, war, riots, fire, strike, governmental laws), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed ("**Force Majeure**"). The non-performing Party shall notify the other Party of such Force Majeure within [*] after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance of the affected Party will be of no greater scope and no longer duration than is necessary and the non-performing Party shall use diligent and commercially reasonable efforts to remedy its inability to perform.

17 Entire Agreement; Modification.

The Parties agree to the full and complete performance of the mutual covenants contained in this Agreement. This Agreement, together with the Related Agreements, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by an authorized representative of each of the Parties hereto.

18 [*]

19 Invalid Provision.

If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

20 No Additional Obligations.

BioLineRx and Merck have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than the Study. Neither Party is under any obligation to enter into another type of agreement at this time or in the future.

21 Governing Law

This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without reference to its conflicts of laws principles. The U.N. Convention on the Sale of Goods shall not apply to this Agreement.

22 Dispute Resolution.

22.1 *Negotiation*. The Parties shall attempt in good faith to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any dispute that is not an Excluded Dispute arising between the Parties relating to, arising out of, or in any way connected with this Agreement, or any term or condition hereof, or the performance by either Party of its obligations hereunder (a "**Dispute**"), whether before or after expiration or termination of this Agreement, which is not resolved by the Parties within [*] days after written notice of such Dispute is first given by one Party to the other Party in writing, will be referred to a senior executive (at Vice President level or above) designated by BioLineRx and a senior executive (at Vice President level or above) designated by Merck who are authorized to resolve such Dispute on behalf of their respective companies ("**Senior Executives**"). The Senior Executives will meet (or confer by telephone or video conference) within [*] days after the end of the initial [*] period referred to above, at a time and place acceptable to both Senior Executives. [*]

[*]

23 Notices.

All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier), or sent by internationally-recognized overnight courier addressed as follows:

If to BioLineRx, to:

BioLineRx Ltd.
Modi'in Technology Park
2 HaMa'ayan Street
Modi'in 7177871, Israel
Attention: Chief Financial and Operating Officer

With a copy to:

General Counsel
BioLineRx Ltd.
Same address as above

If to Merck, to:

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
Netherlands
Attention: Director
Facsimile: [*]

With a copy to:

Merck Sharp & Dohme Corp.
One Merck Drive
P.O Box 100
Whitehouse Station, NJ 08889-0100
Attention: Office of Secretary
Facsimile No.: [*]

24 Relationship of the Parties.

The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or take any actions, which are binding on the other Party, except with the prior written consent of the other Party to do so. All Persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

25 Counterparts and Due Execution.

This Agreement and any amendment may be executed in two (2) or more counterparts (including by way of facsimile or electronic transmission), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. For clarity, facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

26 Construction.

Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall be deemed to be followed by the phrase "without limitation" or like expression. The term "will" as used herein means shall. References to "Article," "Section" or "Appendix" are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, references to this "Agreement" shall include the appendices attached to this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the respective authorized representatives of the Parties have executed this Agreement as of the Effective Date.

BioLineRx Ltd.

By: _____

_____
Name

_____
Title

Merck Sharp & Dohme B.V.

By: _____

_____
Name

_____
Title

Appendix A

PROTOCOL SUMMARY [Merck draft dated December 27]

[*]

Appendix B

DELIVERY SCHEDULE

[*]

Appendix C

INITIAL PRESS RELEASE

For Immediate Release
DRAFT: January 8, 2016

BioLineRx Announces Collaboration with MSD to investigate the combination of KEYTRUDA® (pembrolizumab) and BL-8040 in Pancreatic Cancer

BioLineRx management to hold conference call this morning at 10:00 am EST to further discuss this immunotherapy collaboration

Tel Aviv**,** Israel - January xx, 2016 - BioLineRx Ltd. (NASDAQ/TASE: BLRX) today announced a collaboration with MSD, known as Merck in the US and Canada, to support a Phase 2 study investigating BioLineRx's BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic cancer. The study is an open-label, multicenter, single-arm trial designed to evaluate the safety and efficacy of this combination in patients with metastatic pancreatic adenocarcinoma.

BL-8040, BioLineRx's lead oncology platform, is a CXCR4 antagonist that has been shown in several clinical trials to be a robust mobilizer of immune cells and to be effective at inducing direct tumor cell death. Additional findings in the field of immuno-oncology suggest that CXCR4 antagonists may be effective in inducing the migration of anti-tumor T cells into the tumor micro-environment. KEYTRUDA is a humanized monoclonal antibody that works by increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T- lymphocytes, which may affect both tumor cells and healthy cells. The Phase 2 study will evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity.

"We are extremely happy to collaborate with MSD, a pioneer and world leader in cancer immunotherapy. This marks the entrance of BL-8040 into this exciting field, which is already transforming the lives of many cancer patients," stated Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "Because certain tumors exhibit only a modest response to existing immunotherapies, we are increasingly seeing clinical studies involving combinations of immuno-oncology agents with other classes of drugs. We are initiating this study with the hope that it will show that the combination of BL-8040 with KEYTRUDA has the potential to expand the benefit of immunotherapy to cancer types currently resistant to immuno-oncology treatments, such as pancreatic cancer, which represents a significant unmet medical need. If this potential can be realized, it will be an extremely important advance in the fight against cancer, as well as a seminal milestone for BioLineRx."

“Today, there is a great opportunity and need to bring forward new scientific breakthroughs for the treatment of pancreatic cancer,” said Dr. Eric Rubin, vice president and therapeutic area head, oncology early-stage development, MSD Research Laboratories. “Evaluating the potential of combination therapies through strategic collaborations in difficult-to-treat tumor types continues to be an important part of our immuno-oncology clinical development program for KEYTRUDA.”

The agreement is between BioLineRx and MSD, through a subsidiary. Per the terms of the agreement, the trial will be sponsored and performed by BioLineRx. The study is planned to commence by mid-2016. Upon completion of the study, or at any earlier point, both parties will have the option to expand the collaboration to include a pivotal registration study. Additional details of the collaboration were not disclosed.

BioLineRx will hold a conference call to discuss the collaboration today, January xx, 2016, at 10:00 am EST. To access the conference call, please dial 1-888-281-1167 from the U.S. or +972-3-918-0610 internationally. The call will also be available via live webcast through BioLineRx’s website. A replay of the conference call will be available approximately two hours after completion of the live conference call. To access the replay, please dial 1-888-326-9310 from the U.S. or +972-3-925-5904 internationally. The replay will be available through January xx, 2016.

About Pancreatic Cancer
There are a number of types of pancreatic cancer. Based on available worldwide numbers, in 2012, pancreatic cancers of all types were the seventh most common cause of cancer deaths. According to the American Cancer Society, in 2015 nearly 50,000 were diagnosed with pancreatic cancer and an estimated 40,000 will die from the disease. The most common type of pancreatic cancer is pancreatic adenocarcinoma, which accounts for about 85 percent of cases. These adenocarcinomas start within the part of the pancreas that makes digestive enzymes. There are usually no symptoms in the early stages of the disease and symptoms that are specific enough to suggest the onset of pancreatic cancer typically do not develop until the disease has reached an advanced stage. The five-year survival rate of pancreatic adenocarcinoma is around 7 percent.

About BL-8040
BL-8040 is a short peptide for the treatment of acute myeloid leukemia, solid tumors, and certain hematological indications. It functions as a high-affinity antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. CXCR4 is over-expressed in more than 70% of human cancers and its expression often correlates with disease severity. In a number of clinical and pre-clinical studies, BL-8040 has shown robust mobilization of cancer cells from the bone marrow, thereby sensitizing these cells to chemo- and bio-based anti-cancer therapy, as well as a direct anti-cancer effect by inducing apoptosis. In addition, BL-8040 has also demonstrated robust stem-cell mobilization, including the mobilization of colony-forming cells, and T, B and NK cells. BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

About BioLineRx
BioLineRx is a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates. The Company in-licenses novel compounds primarily from academic institutions and biotech companies based in Israel, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's leading therapeutic candidates are: BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for relapsed/refractory AML, has recently initiated a Phase 2b study as an AML consolidation treatment, has recently initiated a Phase 1/2 study in hMDS and AA, and has successfully completed a Phase 1 study in stem cell mobilization; and BL-7010 for celiac disease, which has successfully completed a Phase 1/2 study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates.

For more information on BioLineRx, please visit www.biolinerx.com or download the investor relations mobile device app, which allows users access to the Company's SEC documents, press releases, and events. BioLineRx's IR app is available on the iTunes App Store as well as the Google Play Store.

Various statements in this release concerning future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" sections of recent annual reports filed by the parties to this release. In addition, any forward-looking statements represent the parties' views only as of the date of this release and should not be relied upon as representing their views as of any subsequent date. The parties do not assume any obligation to update any forward-looking statements unless required by law.

Contact:
PCG Advisory
Vivian Cervantes
Investor Relations
212-554-5482
vivian@pcgadvisory.com

or

Tsipi Haitovsky
Public Relations
+972-3-624-0871
tsipihai5@gmail.com

Schedule I

DATA SHARING AND SAMPLE TESTING SCHEDULE

[*]

SCHEDULE 2.4

Potential BioLineRx Subcontractors
(in accordance with Section 2.4)

[*]

EXHIBIT 4.19

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [*] INDICATES THAT INFORMATION HAS BEEN REDACTED.

CONFIDENTIAL

AMENDMENT NO. 2 TO
CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT
(FOR PANCREATIC CANCER STUDY)

This Amendment No. 2 to the CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT (this "**Amendment No. 2**"), made as of the date of last signature hereunder (the "**Amendment No. 2 Effective Date**"), is by and between Merck Sharp & Dohme B.V. ("**Merck**") and BioLineRx Ltd. ("**BioLineRx**"). Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Agreement.

WHEREAS, the Parties entered into a Clinical Trial Collaboration and Supply Agreement effective January 11, 2016 and amended it as of the same date (such agreement, as amended, will be referred to hereunder as the "**Agreement**"); and

WHEREAS, the Parties wish to amend certain provisions of the Agreement, including with respect to the supply of the Compounds.

NOW, THEREFORE, the Parties hereby agree as follows:

1 Section 1.65 of the Agreement is hereby deleted in its entirety and replaced with the following

"1.65. "**Protocol**" means the written documentation that describes the Study and sets forth specific activities to be performed as part of the Study conduct, a copy of which in its approved final form is attached hereto as Appendix A."

2 Section 4.1 of the Agreement is hereby deleted in its entirety and replaced with the following.

"4.1. *Protocol*. The approved final Protocol is attached hereto as Appendix A. BioLineRx shall provide any subsequent proposed revisions to the approved final Protocol to Merck for Merck's review and comment, consistent with the remaining provisions of this Section 4.1.

4.1.1. Notwithstanding the provisions of Section 4.1, each Party shall have the following decision rights:

a) Any further, material changes to the approved final Protocol (other than relating solely to the BioLineRx Compound) and [*] shall require Merck's prior written consent. Any such proposed changes will be sent in writing to Merck's Project Manager and Merck's Alliance Manager. Merck will provide such consent, or a written explanation for why such consent is

being withheld, within [*] Business Days of receiving a copy of BioLineRx's requested changes.

b) [*]

c) [*]

3 Section 8.1 of the Agreement is hereby deleted in its entirety and replaced with the following.

"8.1. *Supply of the Compounds*. Subject to the terms and conditions of this Agreement, BioLineRx and Merck will each use commercially reasonable efforts to supply, or cause to be supplied, such quantities of its Compound in accordance with the delivery schedule set forth on Appendix B. In the event that BioLineRx determines that the quantities of Compounds as set forth on Appendix B are not sufficient to complete the Study, BioLineRx shall so notify Merck in writing, and the Parties shall discuss in good faith regarding whether additional quantities of Compounds may be provided and the schedule on which such additional quantities may be provided. Each Party shall also provide to the Party a contact person for the supply of its Compound under this Agreement. [*]."

4 Appendix A of the Agreement is hereby deleted in its entirety and replaced with the new Appendix A, which is attached to this Amendment No. 2 as Exhibit 1.

5 Appendix B of the Agreement is hereby deleted in its entirety and replaced with the new Appendix B, which is attached to this Amendment No. 2 as Exhibit 2.

6 Schedule I of the Agreement is hereby deleted in its entirety and replaced with the new Schedule I, which is attached to this Amendment No. 2 as Exhibit 3.

7 The remaining provisions of the Agreement shall remain in full force and effect Upon execution of this Amendment No. 2 by both Parties, all references in the Agreement to the "Agreement" shall mean the Agreement as modified by this Amendment No. 2.

8 This Amendment No. 2 may be executed in two (2) or more counterparts as set forth in the Agreement.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the respective authorized representatives of the Parties have executed this Amendment No. 2 on the date set forth under the signatures below.

BioLineRx Ltd.

By: /s/ Philip Serlin

Philip Serlin
Name

Chief Executive officer
Title

24-July-2018
Date

Merck Sharp & Dohme B.V.

By: /s/ P. R. Koopman

P. R. Koopman
Name

Proxy Holder
Title

July 17, 2018
Date

Exhibit 1

Appendix A PROTOCOL

[*]

Exhibit 2

Appendix B DELIVERY SCHEDULE

[*]

Exhibit 3

Schedule I

DATA SHARING AND SAMPLE TESTING SCHEDULE

[*]

Exhibit 4.22

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [*] INDICATES THAT INFORMATION HAS BEEN REDACTED.

CONFIDENTIAL

Execution Copy

PATENT & KNOW-HOW

LICENSE AGREEMENT

THIS AGREEMENT dated September 19, 2017 is between the following Parties:

(1) **KODE BIOTECH LIMITED**, a New Zealand limited company (company no. 713905) having its registered office at 19 Mount Street, Scott Laboratory Building, Auckland University of Technology, Auckland (the "**Licensor**"); and

(2) **AGALIMMUNE LTD.**, a private limited company incorporated in England and Wales (company no. 08504603) having its registered office at 1st Floor, Thavies Inn House, 3-4 Holborn Circus, London EC1N 2HA (the "**Licensee**").

Background

A. The Licensor has developed a range of water dispersible glycan-lipid conjugates and is the owner of Exclusionary Rights in respect of the KODE™ Constructs and associated KODE™ Know how.

B. The Licensee undertakes research into tumour anticancer therapy in humans and is developing a method of promoting tumour regression and destruction by the administration of glycolipids comprising the α-gal epitope.

C. On March 31, 2015 the Licensee was granted by the Licensor the right to require the Licensor to enter into a license to pursue clinical development and commercialisation of the use of the KODE™ Technology as part of its method ("**Option**").

D. The Licensee has exercised its Option by delivery of an "**Option Exercise Notice**" as referred to in the Option, and this Agreement accordingly sets out the terms and conditions of the license granted by the Licensor.

IT IS AGREED as follows:

1 Definitions and Interpretation

1.1 Definitions. In this Agreement (including the Background), the following words shall have the following meanings:

Affiliate: means an entity that controls, is controlled by, or is under common control with a Party to this Agreement. The term "control" as used in the preceding sentence means possession of the power to direct or call for the direction of the management and policies of an entity, whether through ownership of a majority of the outstanding voting securities, by contract, or otherwise.

Agalimmune Patent: means the patent application by the Licensee listed in Part 2 of Schedule 1 together with any and all granted patents, continuations, continuations-in-part, divisionals, extensions, reissues, supplementary protection certificates and similar rights that are based on or derive priority from the foregoing.

Confidential Information: means any confidential or proprietary information (including without limitation any trade secrets, Exclusionary Rights, and any inventions, designs, information, know-how, specifications, formulae, data, processes, methods, techniques and other technology) in any form belonging or relating to one Party (the "**Disclosing Party**"), its Affiliates, its or their business or affairs and directly or indirectly furnished to the other Party (the "**Receiving Party**") in connection with this Agreement.

Control: in relation to a body corporate, the power of a person to secure that the affairs of the body corporate are conducted in accordance with the wishes of that person (or persons):

(a) by means of the holding of shares, or the possession of voting power, in or in relation to, that or any other body corporate; or

(b) by virtue of any powers conferred by the constitutional or corporate documents, or any other document, regulating that or any other body corporate,

and a **Change of Control** occurs if a person who controls any body corporate ceases to do so or if another person acquires control of it.

Exclusionary Rights: Intellectual property or other proprietary rights (such as registered designs, patents and registered trademarks) that provide the right to exclude others from using the claimed subject matter.

Dollar or **$:** US Dollar.

Effective Date: The date of delivery of the Option Exercise Notice.

Field: Treatment of cancer in humans whether by way of intramural injection or direct application to tumours.

KODE™ Constructs: [*]

KODE™ Know-How: all know-how owned by the Licensor relating to KODE™ Technology that is not generally known and is useful or necessary for the Licensee to enjoy the benefits of the right and licence granted by the Licensor under Clause 2 including Regulatory Documentation, and all pre-clinical and clinical data owned by the Licensor that is relevant to the Licensed Product. Examples of the KODE™ Know-How include, without limitation, all technical, scientific and other know-how, information and data, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including pre-clinical and clinical trial results (including Regulatory Documentation), manufacturing procedures, test procedures and purification and isolation techniques, whether or not confidential, proprietary, patented or patentable.

KODE™ Technology: The KODE™ Constructs, their preparation, and biological entities (including cells and virions) incorporating or prepared using KODE™ Constructs.

LCIA: The London **Court of International Arbitration.**

Licensed Patents: All KODE Technology granted patents and applications owned by the Licensor including those listed in Part 1 of Schedule 1 together with any improvements, continuations, continuations-in-part, divisionals, extensions, reissues, supplementary protection certificates and similar rights that are based on or derive priority from the foregoing. The Licensed Patents also include any granted patents and applications forming part of the New Rights created or acquired by the Licensor during the Term.

Licensed Product: A product in the Field that cannot be developed, manufactured, used, or sold without infringing one or more Valid Claims.

Net Sales: means the actual invoiced amount on sales of Licensed Products in arm's length transactions by the Licensee (and/or its Affiliates or a Sublicensee as applicable), less the following:

(a) customary trade, quantity, or cash discounts to non-affiliated brokers or agents to the extent actually allowed and taken;

(b) amounts repaid or credited by reason of rejection or return;

(c) to the extent identified on the invoice, any costs of packing, insurance, transport, delivery; and

(d) to the extent separately stated on purchase orders, invoices, or other documents of sale, any taxes or other governmental charges levied on the production, sale, transportation, delivery, or use of a Licensed Product which is paid by or on behalf of the Licensee (or the applicable Affiliates or Sublicensee).

In any transfers of Licensed Products between any of the Licensee and its Affiliates (or a Sublicensee and its Affiliates as applicable), Net Sales are subject to and calculated based on the final sale of the Licensed Product to an independent Third Party. If non-monetary consideration is received for any Licensed Products, Net Sales are calculated based on the fair market value of that consideration. If a Licensed Product is used or disposed of by the Licensee (or its Affiliate or the Sublicensee as applicable) in the provision of a commercial service, the Licensed Product is sold and the Net Sales are calculated based on the sales price of the Licensed Product to an independent Third Party during the same Royalty Period or, in the absence of sales, on the fair market value of the Licensed Product as determined by the Parties in good faith.

New Rights has the meaning given in Clause 6.2(a).

Parties: The Licensor and the Licensee and their respective permitted successors and assigns, and '**Party**' shall mean each of them.

Regulatory Approval: Means any and all approvals (including pricing and reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority, necessary for the marketing and sale of a Licensed Product in a country.

Regulatory Authority: Means any applicable government entities regulating or otherwise exercising authority with respect to the manufacturing, marketing, sale, reimbursement and/or pricing of the Licensed Products in the Territory, including, without limitation, in the United States, the United States Food and Drug Administration, and in the European Union, the European Medicines Agency, and any successor governmental authority having substantially the same function.

Regulatory Documentation: Means (a) all applications, registrations, licenses, authorizations and approvals submitted to or received from Regulatory Authorities by Licensor, (b) all correspondence submitted to or received from Regulatory Authorities by Licensor, (c) minutes and official contact reports relating to any communications by Licensor with any Regulatory Authority, (d) all supporting documents and all clinical studies and tests by Licensor, relating to any Licensed Product, and (e) all data contained in any of the foregoing, including all advertising and promotion documents, adverse event files and complaint files, but excluding any and all Regulatory Approvals with respect to such Licensed Product.

Royalty Period: means the partial calendar quarter commencing on the date on which the first sale of a Licensed Product is entered into (including for clarity by a Sublicensee) and every complete or partial calendar quarter thereafter during which either:

(a) this Agreement remains in effect; or

(b) the Licensee has the right to complete and sell work-in-progress and inventory of Licensed Products.

Sublicensee: means any sublicensee of the rights granted the Licensee under this Agreement, and "**Sublicense**" shall be construed accordingly.

Sublicense Net Sales: means Net Sales by a Sublicensee.

Sublicense Royalties: means royalties due to and received by the Licensee under a Sublicense in respect of sales of Licensed Products.

Term: The period defined in Clause 8.1.

Third Party: Any person other than a Party.

Valid Claim: means:

(a) a claim of an issued and unexpired patent covering the Licensed Patents which has not been permanently revoked or held unenforceable or invalid by an unappealable or unappealed decision of a court or government agency of competent jurisdiction; or

(b) a claim of a pending patent application within the Licensed Patents that has not been abandoned or finally disallowed within [*] years of the first filing date without the possibility of appeal or refiling.

For the purposes of Clause 8.1 (Commencement and termination by expiry) Valid Claims shall be construed with regard to the Agalimmune Patent mutatis mutandis.

1.2 Interpretation. Except where otherwise stated, any reference in this Agreement to a Clause or a Schedule is to a Clause of or a Schedule to this Agreement. The provisions of the Schedules shall form part of this Agreement as if set out here. The headings and sub-headings in this document are inserted for convenience only and shall not affect the construction or interpretation of this Agreement.

2 License

2.1 Grant of License. For the Term, and subject to the provisions of this Agreement, the Licensor hereby grants to the Licensee a worldwide, exclusive, royalty-bearing, transferable license in the Exclusionary Rights under the Licensed Patents to:

(a) use the KODE™ Technology and KODE™ Know-how in the Field; and

(b) develop, have developed, make, have made, use, have used, import, have imported, sell and have sold Licensed Products.

The Licensor undertakes not to grant others the right to exploit the Exclusionary Rights under the Licensed Patents in the Field during the Term.

2.2 Additional Know-how. The Licensor shall promptly make available to the Licensee such further KODE™ Know-how as the Licensor acquires after the date of this Agreement and is at liberty to disclose to the Licensee for commercial use. Such further KODE™ Know-how so supplied by the Licensor under this Clause shall, where it has been identified by describing and recording it when provided to the Licensee, be deemed to be part of the KODE™ Know-how. Nothing in this Agreement shall constitute any representation or warranty that any such further KODE™ Know-how supplied to the Licensee pursuant to this Clause is accurate, up to date, complete, or relevant to the KODE™ Technology or the manufacture of the Licensed Products.

2.3 Sublicenses. The Licensee may grant Sublicenses of its rights licensed under this Agreement. All Sublicenses executed by the Licensee pursuant to this Clause shall expressly bind the Sublicensee to the relevant terms of this Agreement. The Licensee shall promptly furnish the Licensor with a fully executed copy of any Sublicense.

2.4 Retained Rights. For the avoidance of doubt the Licensor retains the right to use and exploit the Exclusionary Rights under the Licensed Patents outside of the Field.

2.5 Supply and Use of KODE™ Constructs. To enable the Licensee to enjoy the benefits of the right and licence granted by the Licensor hereunder the Licensee will from time to time require a reliable, good quality supply of KODE™ Constructs. The Licensor shall take commercially reasonable steps during the term of this licence to ensure that at all material times one or more suppliers (each an "**Authorised KODE™ Construct Manufacturer & Supplier**") is granted a license to enable the manufacture and supply of KODE™ Constructs to the Licensee. Each such licence shall:

(a) require the Authorised KODE™ Construct Manufacturer & Supplier to ensure that all KODE™ Constructs supplied to the Licensee are, as a minimum, manufactured in accordance with [*] as certified by the Licensor (or an appropriate independent third party certifier approved by the Licensor); and

(b) provide that the Licensor's royalties for such licence shall not exceed a margin of [*] over the Authorised KODE™ Construct Manufacturer & Supplier's costs of goods manufactured.

The Licensor shall give reasonable consideration to (if applicable) a proposal or proposals from time to time by the Licensee for:

(c) the Licensee itself to become an Authorised KODE™ Construct Manufacturer & Supplier; and/or

(d) for a Third Party to become an Authorised KODE™ Construct Manufacturer & Supplier,

subject always to agreeing commercially reasonable quality and supply terms for the manufacture and supply KODE™ Constructs for the Licensee. Such a license is required to be separately negotiated with the Licensor.

The terms set forth in clause 1 of the Letter Agreement dated 18 March 2017, as amended, between the Licensor and the Licensee are incorporated in this Agreement as though fully set forth herein, thereby granting the Licensee a license to be an Authorised KODE™ Construct Manufacturer & Supplier as contemplated by this clause 2.5.

3 Diligence and Commercialisation Requirements

3.1 Diligence Requirements. The Licensee shall use reasonable diligent efforts or require its Affiliates and Sublicensees to use reasonable diligent efforts to develop at least one Licensed Product and to introduce such Licensed Product into the commercial market.

3.2 Development Plans & Reports. The Licensee shall furnish the Licensor with plans and reports as follows:

Plans & Report	Due Date
A written business plan under which the Licensee intends as of the Effective Date to develop and commercialize Licensed Products	Within [*] days of the Effective Date
A written update of the business plan including without limitation: · research and development progress during the prior year; · efforts to obtain regulatory approval during the prior year; · marketing, and sales figures during the prior year; · a discussion of its intended development and commercialisation efforts; and · sales projections for the current year.	Within [*] days after the start of each calendar year, beginning on 1 January 2016

3.3 Compliance.

(a) KODE™ Constructs. The Licensee shall comply with all applicable laws, regulations and guidelines relevant to the use of KODE™ Constructs.

(b) Licensed Products Compliance. The Licensee shall take all reasonable steps to comply with, and shall require that its Affiliates and Sublicensees comply with, all local, state, federal, and international laws and regulations relating to the development, testing, manufacture, use, and sale of Licensed Products. The Licensee expressly agrees to comply with the following:

(i) The Licensee or its Affiliates or Sublicensees shall obtain all necessary approvals from the United States Food & Drug Administration and any similar foreign governmental authorities in countries or regions in which the Licensee or Affiliate or Sublicensee intends to make, use, or sell Licensed Products.

(ii) The Licensee and its Affiliates and Sublicensees shall comply with all United States laws and regulations controlling the export of commodities and technical data, including without limitation all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit or require a license for the export of certain types of commodities and technical data to specified countries and foreign nationals. The Licensee hereby gives written assurance that it will comply with and will cause its Affiliates and Sublicensees to comply with all United States export control laws and regulations, that it bears sole responsibility for any violation of those laws and regulations by itself or its Affiliates or Sublicensees.

3.4 Use of Licensor Name. In accordance with Clause 7.2, but subject to Clause 3.5, the Licensee and its Affiliates and Sublicensees may not use the name "KODE Biotech Ltd" or any variation of that name in connection with the marketing or sale of any Licensed Products without prior consent.

3.5 Use of Trademarks. The Licensee shall be entitled to use (and to grant the right to Sublicensees to use) the KODE™ trademark and other relevant trademarks of Licensor in the form and manner approved by the Licensor (acting reasonably) on or in relation to Licensed Products manufactured and sold, including without limitation use in brochures and marketing materials, provided always that such use is legally permissible. The Licensee will submit sample copies of the proposed use (including the details of proposed package inserts, packaging or promotional or advertising materials) to the Licensor for approval, such approval not to be unreasonably withheld or delayed. The Licensor hereby grants to the Licensee the non-exclusive right to use the KODE™ trademark and other relevant Licensor trademark(s) as contemplated in accordance with the terms of and for the duration of this agreement.

3.6 Marking of Licensed Products. To the extent commercially feasible and consistent with prevailing business practices, the Licensee shall mark and shall cause its Affiliates and Sublicensees to mark all Licensed Products that are manufactured or sold under this Agreement with the number of each issued patent under the Licensed Patents that applies to a Licensed Product.

3.7 Indemnity.

(a) Indemnitees. The Licensee shall indemnify the Licensor, its agents and employees ("**Indemnitees**") against all Claims and Losses arising from the Licensee's receipt, use, or keeping of KODE™ Constructs, provided that the Licensee shall have no liability to the extent any Claim or Loss is directly attributable to the negligence or intentional misconduct of the Licensor or its officers, employees, and agents, or for any special incidental, consequential or punitive damages. '**Claims**' shall mean all demands, claims, proceedings, penalties, fines, and liability (whether criminal or civil, in contract, tort, or otherwise), and '**Losses**' shall mean all losses including without limitation financial losses, damages, reasonable legal costs, and other reasonable expenses of any nature.

(b) Procedures. The Indemnitees agree to provide the Licensee with prompt written notice of any claim, suit, action, demand, or judgment for which indemnification is sought under this Agreement. The Indemnitees shall cooperate fully with the Licensee in the defence and will permit the Licensee to conduct and control the defence and the disposition of the claim, suit, or action (including all decisions relative to litigation, appeal, and settlement). However, any Indemnitee may (acting reasonably) retain its own counsel, at the expense of the Licensee, if representation of the Indemnitee by the counsel retained by the Licensee would be inappropriate because of actual or potential conflicts in the interests of the Indemnitee and any other party represented by that counsel. The Licensee agrees to keep the Licensor reasonably informed of the progress in the defence and disposition of the Claim and to consult with the Licensor regarding any proposed settlement.

(c) Insurance. The Licensee shall maintain insurance that is reasonably sufficient to fulfil its obligations under this Agreement, including the following:

Effective Date	Insurance	Coverage
Commencing on the Effective Date	Employers' liability insurance	Statutory limits as required by law
Commencing as of 1 October 2017	Commercial general liability insurance	[*]
Upon commencing testing or sales	Clinical trials insurance (upon commencing testing) / product liability insurance (upon sale)	[*]
In connection with the conduct of any clinical testing	Professional liability insurance (errors and omissions)	[*]

(i) Upon commencement of coverage (as required above) and thereafter annually upon renewal, the Licensee shall provide the Licensor with written evidence of insurance.

(ii) Such insurance shall list the Licensor as an additional insured. All policies shall be endorsed to indicate that they provide primary coverage without right of contribution by any insurance carrier or self-insured by the Licensor. A waiver of subrogation in favour of the indemnitees shall also be endorsed to the policies. If such coverage is not written on an "occurrence" basis (i.e., it is written on a "claims made" basis), the Licensee shall maintain such insurance coverage during the term of this Agreement and for five (5) years thereafter.

(iii) For purposes of this Clause, references to the "Licensee" shall include any Affiliate of the Licensee to which the Licensee grants a sublicense hereunder or to which it otherwise delegates any of the Licensee's obligations hereunder, and the Licensee shall ensure that the foregoing insurance obligations shall apply to any such Affiliate.

4 Consideration

4.1 Licence Fee. In partial consideration of the rights granted under this Agreement, the Licensee shall pay to the Licensor the following licence issue fee

Event	Payment
Within [*] days after the first anniversary of the Effective Date	[*]

This license issue fee payment is non-refundable and is not creditable against any other payments due to the Licensor under this Agreement.

4.2 Maintenance Fees. The Licensee shall pay to the Licensor the following licence maintenance fees:

Event	Payment
Within [*] days after each anniversary of the Effective Date	[*]

These license maintenance fee payments are non-refundable and are not creditable against any other payments due to the Licensor under this Agreement.

4.3 Milestone Payments. The Licensee shall pay to the Licensor the following milestone payments:

Event	Payment
Within [*] days after initiation of first Phase III Clinical Trial of a Licensed Product (initiation being first dose of first patient)	[*]
Within [*] days after approval of first Licensed Product for a first indication	[*]
Within [*] days after first commercial sale of a first Licensed Product following approval for use in humans	[*]
Within [*] days after the financial year end of the first financial year in which net sales of Licensed Products for use in humans achieve not less than [*]	[*]

These milestone payments are non-refundable and are not creditable against any other payments due to the Licensor under this Agreement.

4.4 Net Sales Royalties. The Licensee shall pay to the Licensor royalties in respect of its sales of Licensed Products as follows:

Net Sales	Payment
Net Sales in [*]	[*]
Net Sales in [*]	[*]

4.5 Sublicense Royalties. The Licensee shall pay to the Licensor royalties in respect of sales of Licensed Products by each Sublicensee as follows:

(a) The greater of:

(i) [*]

(ii) [*]

(b) The greater of:

(i) [*]

(ii) [*]

4.6 Change of Control. In order that the royalty rates in Clause 4.5 in respect of sales of Licensed Products by each Sublicensee shall not be circumvented, if a Sublicensee or affiliated party acquires Control of the Licensee, and within [*] months the Sublicense previously held by such Sublicensee is terminated, then with effect from the date of termination of the Sublicense the royalty rates payable by the Licensee to the Licensor pursuant to Clause 4.4 in respect of those sales of Licensed Products which would otherwise have been sold pursuant to the applicable Sublicense shall be adjusted to such rate as preserves the effective royalty rate to which the Licensor was entitled immediately prior to termination of the Sublicense.

4.7 No Multiple Royalties. No multiple royalties shall be payable because any Licensed Product is covered by more than one Licensed Patent.

4.8 Buy Out. The Licensor shall give reasonable consideration to any proposal by the Licensee (or its assignee or successor) for a one-time lump sum payment in full consideration of all future payment obligations to the Licensor under this Agreement, including, without limitation, royalties, milestone payments, license maintenance fees and manufacturing royalties; provided, however that the Licensor shall have the right in its sole discretion to reject any and all proposals for any reason whatsoever or for no reason at all.

5 Royalty Reports; Payments; Records

5.1 First Sale. The Licensee shall report to the Licensor the date of:

(a) First manufacture and supply of KODE™ Constructs within [*] days after occurrence by the Licensee and by each Authorised Manufacturer & Supplier; and

(b) First commercial sale (whether by the Licensee, or its Affiliate or any Sublicensee) of each Licensed Product within [*] days after occurrence in each country.

5.2 Reports and Payments.

(a) Within [*] days after the conclusion of each Royalty Period, the Licensee shall deliver to the Licensor a report containing the following information:

(i) With regard to KODE™ Constructs acquired, the identity of the Authorised KODE™ Construct Manufacturer & Supplier(s) and the volumes of KODE™ Construct purchased, and the Licensor will promptly thereafter provide such information as reasonably required to verify its margin royalty in respect of such supplies;

(ii) With regard to the royalties payable in respect of Licensed Products:

A the number of Licensed Products sold to independent third parties in each country;

B the gross sales price for each Licensed Product by the Licensee and its Affiliates during the applicable Royalty Period in each country;

C the calculation of Net Sales for the applicable Royalty Period in each country, including a listing of applicable deductions with specific identification of the Russian Federation; and

D total royalties payable on Net Sales in United States dollars, together with the exchange rates used for conversion; and

(iii) With regard to royalties due to the Licensor in respect of Sublicenses for the applicable Royalty Period:

A details of the identity of the Sublicensees;

B the gross Sublicense Net Sales during the applicable Royalty Period;

C the gross Sublicense Royalties during the applicable Royalty Period; and

D the calculation of the and total, amount due to the Licensor in respect of the Sublicense for the applicable Royalty Period in United States dollars, together with the exchange rates used for conversion.

Concurrent with this report, the Licensee shall remit to the Licensor any payment due for the applicable Royalty Period. If no amounts are due to the Licensor for any Royalty Period, the report shall so state.

5.3 Payments in United States Dollars. The Licensee shall make all payments in United States dollars. The Licensee shall convert foreign currency to United States dollars at the conversion rate existing in the United States (as reported in the Wall Street Journal) on the last working day of the calendar quarter preceding the applicable Royalty Period. The Licensee may not deduct exchange, collection, or other charges.

5.4 Payments in Other Currencies. If by law, regulation, or fiscal policy of a particular country, conversion into United States dollars or transfer of funds of a convertible currency to the United States is restricted or forbidden, the Licensee shall give the Licensor prompt written notice of the restriction within the [*] reporting and payment deadline for each Royalty Period. The Licensee shall pay any amounts due the Licensor through whatever lawful methods the Licensor reasonably designates. However, if the Licensor fails to designate a payment method within [*] days after the Licensor is notified of the restriction, the Licensee may deposit payment in local currency to the credit of the Licensor in a recognized banking institution selected by the Licensee and identified by written notice to the Licensor, and that deposit fulfils all obligations of the Licensee to the Licensor with respect to that payment.

5.5 Records. The Licensee shall maintain and shall cause its Affiliates and require its Sublicensees to maintain complete and accurate records of Licensed Products that are made, used, or sold under this Agreement and any amounts payable to the Licensor in relation to Licensed Products with sufficient information to permit the Licensor to confirm the accuracy of any reports delivered to the Licensor under Clause 5.2.

(a) The relevant party shall retain records relating to a given Royalty Period for at least [*] years after the conclusion of that Royalty Period, during which time the Licensor may, at its expense, cause its internal accountants or an independent, certified public accountant to inspect records during normal business hours for the sole purpose of verifying any reports and payments delivered under this Agreement.

(b) The accountant may not disclose to the Licensor any information other than information relating to accuracy of reports and payments delivered under this Agreement.

(c) The Parties shall reconcile any underpayment or overpayment within [*] days after the accountant delivers the results of the audit.

(d) If any audit performed under this Clause 5.5 reveals an underpayment in excess of [*] percent [*] in any Royalty Period, the Licensee shall bear the full cost of the audit; if less than [*] percent [*] the Licensor shall bear its own costs.

(e) The Licensor may exercise its rights under this Clause 5.5 only once every year and only with reasonable prior notice to the Licensee (or other relevant party).

5.6 Late Payments. Any payments due to the Licensor by the Licensee that are not paid on or before the date payments are due under this Agreement bear interest at [*] per month, calculated on the number of days that payment is delinquent.

5.7 Method of Payment. All payments under this Agreement should be made to "KODE Biotech Limited" and sent to the address identified below. Each payment should reference this Agreement and identify the obligation under this Agreement that the payment satisfies.

5.8 Withholding and Similar Taxes. Royalty payments and other payments due to the Licensor under this Agreement may not be reduced by reason of any withholding or similar taxes applicable to payments to the Licensor. Therefore all amounts owed to the Licensor under this Agreement are net amounts and shall be grossed-up to account for any withholding taxes, value-added taxes or other taxes, levies or charges. In the event that the Licensor shall receive any repayment of any such tax or of any credit obtained by reference to any such deduction that is attributable to such tax, the Licensor shall pay, or shall procure that there is paid, to the Licensee an amount equivalent to the amount overpaid.

6 Intellectual Property and Exclusionary Rights

6.1 Existing Exclusionary Rights. It is expressly agreed that all Exclusionary Rights are and shall [*]. It is further expressly agreed that the license granted by the Licensor hereunder is for the Term and no further rights to use KODE™ Technology and KODE™ Know-How are granted under this Agreement.

6.2 New Exclusionary Rights.

(a) The ownership of any Exclusionary Rights in respect of any discoveries, innovations or inventions made jointly by the Parties during the Term, and capable of being protected under patent law, shall be allocated according to the flowchart appended to this Agreement as Schedule 2 ("**New Rights**").

(b) The Licensor acknowledges that the Licensee will be solely responsible for prosecuting, maintaining and defending any New Rights assigned to the Licensee, in addition to any other patent rights owned solely by the Licensee.

(i) Where in accordance with the flowchart at Schedule 2 the subject matter defined in a New Rights claim provided in the specification does not consist of KODE™ Technology, and the New Rights claim is not in respect of KODE™ Technology, and the Licensee is allocated the rights in respect of the claimed subject matter, the Licensor shall at the Licensee's reasonable request do all such acts and execute all such documents reasonably required by the Licensee to confirm that title in all such New Rights are assigned, or will be assigned to the Licensee, or at the Licensee's option that the Licensor grants or will grant to the Licensee a worldwide, exclusive, royalty-free, transferable license in such New Rights, or one or more specific use, with the right to sublicense. The Licensee shall promptly reimburse all reasonable costs and expenses incurred by the Licensor in connection with providing such assistance. The Licensor acknowledges that no further remuneration or compensation other than that provided for in this Clause is or may become due to the Licensor in respect of the performance of its obligations under this Clause.

(c) The Licensor shall promptly notify the Licensee on becoming aware of any improvement of the KODE™ Technology, or any new KODE™ Technology, that the Licensor believes may have relevance to the Field. The Licensor shall use reasonable endeavours to monitor developments by other KODE™ Technology licensees.

6.3 Responsibility for Licensed Patents.

(a) The Licensor has primary responsibility at its expense and under its own control for the preparation, filing, prosecution, and maintenance of all Licensed Patents. The Licensor shall advise the Licensee as to the preparation, filing, prosecution, and maintenance of all Licensed Patents reasonably prior to any deadline or action with the United States Patent & Trademark Office or any foreign patent office and shall furnish the Licensee with copies of relevant documents reasonably in advance of consultation. The Licensor shall consider in good faith any comments of the Licensee on any patent filings for the Licensed Patents.

(b) If the Licensor desires to abandon any patent or patent application within the Licensed Patents, the Licensor shall provide the Licensee with reasonable prior notice of the intended abandonment, and the Licensee may, at its expense, prepare, file, prosecute, and maintain the relevant Licensed Patents. If the Licensor elects to abandon any patent or patent application or cease payment of any patent expenses, the Licensor loses all rights under this Agreement with respect to the particular Licensed Patents in those one or more countries.

6.4 Cooperation. Each Party shall provide reasonable cooperation in the preparation, filing, prosecution, and maintenance of all Licensed Patents. Cooperation includes, without limitation, promptly informing the other Party of matters that may affect the preparation, filing, prosecution, or maintenance of Licensed Patents (such as, becoming aware of an additional inventor who is not listed as an inventor in a patent application).

6.5 Licensed Patents Infringement.

(a) Notification of Infringement. Each Party agrees to provide written notice to the other Party promptly after becoming aware of any infringement of the Licensed Patents.

(b) Licensor Responsibility for Prosecution in the Field. The Licensor has primary responsibility at its expense for initiating the prosecuting of any third party infringement of the Licensed Patents in the Field and defending the Licensed Patents in any declaratory judgment action brought by a third party which alleges invalidity, unenforceability, or infringement of the Licensed Patents in the Field.

(i) Prior to commencing any action, the Licensor shall consult with the Licensee and shall in good faith consider the views of the Licensee regarding the advisability and conduct of the proposed action and its effect on this Agreement.

(ii) The Licensor shall keep the Licensee reasonably informed of material actions taken by the Licensor pursuant to the infringement or declaratory action.

(iii) The Licensor may not enter into any settlement, consent judgment, or other voluntary final disposition of any infringement action under this Clause without the prior written consent of the Licensee, which consent may not be unreasonably withheld or delayed.

(iv) Any recovery obtained in an action under this Clause shall be distributed as follows: [*].

(c) Licensee as Indispensable Party. If and to the extent required by law, the Licensee shall permit any action under Clause 6.5(b) to be brought in its name, provided that the [*].

(d) Licensee Right to Prosecute. If the Licensor declines or fails to initiate an infringement action within a reasonable time after it first becomes aware of the basis for the action, or to answer a declaratory judgment action within a reasonable time after the action is filed, the Licensee may prosecute the infringement or answer the declaratory judgment action under its [*]. If and to the extent required by law, the Licensor shall permit any such action to be brought in its name, [*]. If the Licensee takes action under this Clause, the Licensee shall keep the Licensor reasonably informed of material actions taken by the Licensee pursuant to the infringement or declaratory action.

(e) Prosecution in Other Fields. If the Licensor or any licensee of the Licensed Patents in a field other than the Field initiates an infringement action the Licensor shall keep the Licensee reasonably informed of material actions taken pursuant to the infringement or declaratory action and shall consider the views of the Licensee regarding the advisability and conduct of the proposed action and its effect on this Agreement.

(f) Cooperation. Both Parties shall cooperate fully in any action under this Clause which is controlled by the other Party, provided that the controlling Party reimburses the cooperating Party promptly for any reasonable costs and expenses incurred by the cooperating Party in connection with providing assistance. Unless it would be unlawful to do so in a particular jurisdiction, the controlling Party may from time to time request the cooperating Party to provide reasonable financial support towards the conduct of an action under this Clause 6.5, and the cooperating Party will give reasonable consideration to such request, having regard (amongst other things) to the advisability and conduct of such action and its effect on this Agreement, the likelihood of the action's prospects of success, and the impact on the cooperating Party if action is not taken or (as the case may be) is discontinued. For clarity any such financial support shall be in the discretion of the cooperating Party and may be subject to such terms and for such duration, or impose such limits or conditions as the cooperating Party may determine.

7 Confidentiality & Publicity

7.1 Confidentiality

(a) Obligations. For [*] years after disclosure of any Confidential Information, the Receiving Party shall:

(i) maintain Confidential Information in confidence, except that the Receiving Party may disclose or permit the disclosure of any Confidential Information to its officers or directors, officers, employees, consultants, and advisors, and those of its Affiliates and Sublicensees who are obligated to maintain the confidential nature of Confidential Information and who need to know Confidential Information for the purposes of this Agreement;

(ii) use Confidential Information solely for the purposes of this Agreement; and

(iii) allow its officers or directors, officers, employees, consultants, and advisors to reproduce the Confidential Information only to the extent necessary for the purposes of this Agreement, with all reproductions being Confidential Information.

The rights of use and reproduction under (ii) and (iii) above shall extend to the Licensee's Affiliates with a need for such use and reproduction as well as to Sublicensees.

(b) Exceptions. The confidentiality obligations of the Receiving Party above do not apply to the extent that the Receiving Party can demonstrate that Confidential Information:

(i) was in the public domain prior to the time of its disclosure under this Agreement;

(ii) entered the public domain after the time of its disclosure under this Agreement through means other than an unauthorized disclosure resulting from an act or omission by the Receiving Party;

(iii) was already known or independently developed or discovered by the Receiving Party without use of the Confidential Information;

(iv) is or was disclosed to the Receiving Party at any time, whether prior to or after the time of its disclosure under this Agreement, by a third party having no fiduciary relationship with the Disclosing Party and having no obligation of confidentiality with respect to the Confidential Information; or

(v) is required to be disclosed to comply with applicable laws or regulations or with a court or administrative order, provided that (to the extent permitted by law) the Disclosing Party receives reasonable prior written notice of the disclosure.

(c) Ownership and Return. The Receiving Party acknowledges that the Disclosing Party (or a Third Party entrusting its own information to the Disclosing Party) owns the Confidential Information in the possession of the Receiving Party. Upon expiration or termination of this Agreement, or at the request of the Disclosing Party, the Receiving Party shall return to the Disclosing Party all originals, copies, and summaries of documents, materials, and other tangible manifestations of Confidential Information in the possession or control of the Receiving Party, except that the Receiving Party may retain one copy of the Confidential Information in the possession of its legal counsel solely for the purpose of monitoring its obligations under this Agreement.

7.2 Publicity Restrictions. The Licensee may not use the name of the Licensor or any of its officers, employees, or agents, or any adaptation of their names, or any terms of this Agreement in any promotional material or other public announcement or disclosure without the prior written consent of the Licensor. The foregoing notwithstanding, the Licensee may disclose that information without the consent of the Licensor in any prospectus, offering memorandum, or other document or filing required by applicable securities laws or other applicable law or regulation, provided that the Licensee provides the Licensor at least [*] days (or a shorter period in order to enable the Licensee to make a timely announcement to fulfil applicable securities laws or other applicable law or regulation, while affording the Licensor the maximum feasible time to review the announcement) prior written notice of the proposed text for the purpose of giving the Licensor the opportunity to comment on the text.

7.3 No information warranty. No warranty or representation is given by either Party as to the accuracy or completeness of information provided under this Agreement. Each Party must make its own independent assessment of the information provided and rely on its own judgment in reaching any conclusion.

8 Term and Termination

8.1 Commencement and termination by expiry. This Agreement, and the licence granted under Clause 2.1 shall come into effect on the Effective Date and, unless terminated earlier in accordance with this Clause 8, shall continue in force and remains in effect until the later of expiration or abandonment of all Valid Claims.

8.2 Voluntary termination. The Licensee may terminate this Agreement:

(a) at any time on [*] days' notice in writing to the Licensor; or

(b) on [*] days' notice if there is a Change of Control of the Licensor, or the Licensor sells all or substantially all of the KODE™ Technology assets to an entity that is a competitor of the Licensee being an entity engaged, directly or indirectly, in any one or more of the development, production, marketing, distribution and/or exploitation of a competing product in the Field.

8.3 Termination by Default. Either Party may terminate this Agreement at any time by notice in writing to the other Party (the '**Other Party'**), such notice to take effect as specified in the notice:

(a) if the Other Party is in persistent breach of this Agreement other than a failure by the Licensee to pay any amount due to the Licensor under this Agreement, and, in the case of a breach capable of remedy within [*] days, the breach is not remedied within [*] days of the Other Party's receiving notice specifying the breach and requiring its remedy; or

(b) If the alleged breach consists of non-payment of any uncontested amounts due to the Licensor under this Agreement, and the Licensee fails to cure that breach within [*] days after receiving notice of the breach, the Licensor may terminate this Agreement immediately upon written notice to the Licensee;

(c) if (A) the Other Party becomes insolvent or unable to pay its debts as and when they become due, or (B) an order is made or a resolution is passed for the winding up of the Other Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction), or (C) a liquidator, administrator, administrative receiver, receiver, or trustee is appointed in respect of the whole or any part of the Other Party's assets or business, or (D) the Other Party makes any composition with its creditors, or (E) the other Party ceases to continue its business, or (F) as a result of debt and/or maladministration the other Party takes or suffers any similar or analogous action in any jurisdiction.

8.4 Force Majeure. Neither Party is responsible for delays resulting from causes beyond its reasonable control, including without limitation fire, explosion, flood, war, strike, act of terrorism or riot, provided that the nonperforming Party uses commercially reasonable efforts to avoid or remove those causes of non-performance and continues performance under this Agreement with reasonable dispatch whenever the causes are removed.

8.5 Consequences of Termination.

(a) Upon the early termination of this Agreement, the Licensee and its Affiliates and Sublicensees may complete and sell any work-in-progress and inventory of Licensed Products that exist as of the effective date of termination, provided that:

(i) the Licensee is current in payment of all amounts due the Licensor under this Agreement,

(ii) the Licensee pays the Licensor the applicable royalty on sales of Licensed Products in accordance with the terms of this Agreement; and

(iii) the Licensee and its Affiliates and Sublicensees complete and sell all work-in-progress and inventory of Licensed Products within nine (9) months after the effective date of termination.

(b) Upon the expiration or termination of this Agreement, for each Sublicensee, upon termination of the Sublicense with such Sublicensee, if the Sublicensee is not then in breach of such Sublicense with the Licensee such that the Licensee would have the right to terminate such Sublicense, the Licensor shall be obligated, at the request of such Sublicensee, to enter into a new agreement with such Sublicensee on substantially the same terms as those contained in such Sublicense; *provided, however*, that such terms shall be amended, if necessary, to the extent required to ensure that such Sublicense agreement does not impose any obligations or liabilities on the Licensor which are not included in this Agreement. The Licensor's consent to such Sublicensee request shall not be unreasonably withheld. Save as expressly provided, upon termination of this Agreement for any reason the Licensee and each Sublicensee shall no longer be licensed to use or otherwise exploit in any way, either directly or indirectly, KODE™ Technology or KODE™ Know-How, in so far and for as long as any of the Licensed Patents remain in force, and except in respect of any accrued rights and those provisions expressed to survive termination, neither Party shall be under any further obligation to the other.

(c) All rights and obligations of the Parties shall cease to have effect immediately upon termination of this Agreement provided that termination shall not affect the continued existence and validity of the rights and obligations of the parties under those Clauses of this Agreement which are expressed to survive termination and any provision of this Agreement necessary for the interpretation or enforcement of this Agreement. A Party's right of termination under this Agreement, and the exercise of any such right, shall be without prejudice to any other right or remedy (including any right to claim damages) that such Party may have in the event of a breach of contract or other default by the other Party.

9 Dispute Resolution.

9.1 Procedures Mandatory. The parties shall resolve any dispute arising out of or relating to this Agreement solely by means of the procedures set forth in this Clause. These procedures constitute legally binding obligations that are an essential provision of this Agreement. If either Party fails to observe the procedures of this Clause, as modified by their written agreement, the other Party may bring an action for specific performance in any court of competent jurisdiction.

9.2 Dispute Resolution Procedures.

(a) Negotiation. In the event of any dispute arising out of or relating to this Agreement, the affected Party shall notify the other Party, and the parties shall attempt in good faith to resolve the matter within [*] days after the date of notice (the "**Notice Date**"). Any disputes not resolved by good faith discussions shall be referred to senior executives of each Party, who shall meet and attempt to negotiate a settlement within [*] days after the Notice Date. Subject as provided the representatives of the Parties may participate in meetings, adjourn and otherwise regulate their meetings as they think fit, and in determining whether such representatives are participating in a meeting, it is irrelevant where any representative is or how they communicate with each other.

(b) Mediation. If the matter remains unresolved within [*] days after the Notice Date, or if the senior executives fail to meet within [*] days after the Notice Date, the Parties shall first seek settlement of that dispute by mediation in accordance with the then current LCIA Mediation Rules, which Rules are deemed to be incorporated by reference into this Clause.

(c) Arbitration. If the Parties fail to resolve the dispute through mediation, or if neither Party elects to initiate mediation, each Party may serve notice on the other Party that it wishes to refer the matters in dispute to be finally resolved by arbitration under the then current LCIA Arbitration Rules, which Rules are deemed to be incorporated by reference into this Clause.

(i) The number of arbitrators shall be one.

(ii) The seat, or legal place, of arbitration shall be London.

(iii) The language to be used in the arbitral proceedings shall be English.

(iv) The governing law of the contract shall be the substantive law of England.

9.3 Preservation of Rights Pending Resolution.

(a) Performance to Continue. Each Party shall continue to perform its obligations under this Agreement pending final resolution of any dispute arising out of or relating to this Agreement. However, a Party may suspend performance of its obligations during any period in which the other Party fails or refuses to perform its obligations.

(b) Provisional Remedies. Although the procedures specified in this Clause are the exclusive procedures for resolution of disputes arising out of or relating to this Agreement, either Party may seek a preliminary injunction or other provisional equitable relief if, in its reasonable judgment, that action is necessary to avoid irreparable harm to itself or to preserve its rights under this Agreement.

(c) Statute of Limitations. The Parties agree that all applicable statutes of limitation and time-based defences (such as, estoppel and laches) are tolled while the negotiation, mediation and/or arbitration procedures set forth in Clause 9.2.(a), 9.2(b) or 9.2(c) are pending. The Parties shall take any actions necessary to effectuate this result.

10 General

10.1 Representations and Warranties. The Licensor warrants that its employees and contractors have assigned to the Licensor their entire right, title, and interest in and to the Licensed Patents, the KODE™ Technology and KODE™ Know-how, and that it has authority to grant the rights and licenses set forth in this Agreement, and that it has not granted any rights in or to the Licensed Patents and/or the KODE™ Technology and/or the KODE™ Know-how to any Third Party that is inconsistent with the grant of rights in this Agreement. Save as expressly provided in this agreement, neither Party makes any other warranty or accepts any liability in connection with the supply and use of KODE™ Constructs hereunder and specifically does not give any warranty that:

(a) [*]

(b) [*]

(c) [*]

10.2 Limitation of liability. Neither Party shall be entitled to recover from the other any special incidental, consequential or punitive damages.

10.3 No Partnership. Nothing in this Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between the Parties, constitute either Party the agent of the other Party, nor authorise either Party to make or enter into any commitments for or on behalf of the other Party.

10.4 Binding Effect. This Agreement is binding upon and inures to the benefit of the Parties and their respective permitted successors and assigns.

10.5 Notices.

Any notices required or permitted under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be (a) delivered personally, or (b) sent by recognized national overnight courier; or (c) sent by registered or certified mail, postage prepaid, return receipt requested, to the following addresses:

If to the Licensor:
KODE Biotech Limited
19 Mount Street
Scott Laboratory Building
Auckland University of Technology
Auckland, New Zealand
Attention: CEO

If to the Licensee:
Agalimmune Limited
c/o Wilson Wright LLP
1st Floor Thavies Inn House
London
United Kingdom EC1N 2HA
Attention: CEO/Director
With a copy to:
BioLineRx Ltd.
2 HaMa'ayan Street
Modi'in 7177871
Israel

Attention: Chief Financial Officer

All notices under this Agreement are effective and deemed received (a) if delivered personally, at the time of delivery; (b) if sent by recognized national overnight courier, two business days from the date of dispatch; (c) in the case of pre-paid registered or certified mail, four business days from the date of posting. If deemed receipt under the previous paragraphs of this Clause is not within business hours (meaning 9.00 am to 5.30 pm Monday to Friday on a day that is not a public holiday in the place of receipt), when business next starts in the place of receipt. To prove service in the case of post, it is sufficient to prove that the envelope containing the notice was properly addressed and posted. A Party may change its contact information immediately upon written notice to the other Party in the manner provided in this Clause.

10.6 Entire agreement. This Agreement sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter, including

(a) the Mutual Confidentiality Undertakings dated 29 July 2014.

(b) Evaluation License & Option Agreement dated 31 March 2015.

The Parties acknowledge that they are not relying on any representation, agreement, term, or condition that is not set out in this Agreement. Nothing in this Agreement excludes liability for fraud.

10.7 Variation & Waiver. This Agreement, including this Clause, may be amended, varied or renewed only by a document in writing signed by a duly authorized representative of each Party. The waiver of any rights or failure to act in a specific instance relates only to that instance and is not an agreement to waive any rights or fail to act in any other instance.

10.8 No assignment. Neither Party shall assign, transfer, charge, encumber, or otherwise deal with the whole or any part of this Agreement, or its rights or obligations under this Agreement without the prior written consent of the other Party which consent may not be unreasonably withheld or delayed. Notwithstanding the foregoing, this Agreement may be assigned by either Party in connection with a merger, consolidation, sale of all of the equity interests of the Party, or a sale of all or substantially all of the assets of the Party to which this Agreement relates save that the prior written consent of Licensee shall be required for an assignment, transfer, or other disposal by Licensor of the whole or any part of this Agreement to a competitor of Licensee being a person engaged, directly or indirectly, in any one or more of the development, production, marketing, distribution and/or exploitation of a competing product in the Field.

10.9 Severability. If any provision of this Agreement is held invalid or unenforceable for any reason, the invalidity or unenforceability does not affect any other provision of this Agreement, and the Parties shall negotiate in good faith to modify the Agreement to preserve (to the extent possible) their original intent. While the dispute is pending resolution, this Agreement shall be construed as if the provision were deleted by agreement of the Parties.

10.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which is an original, and all of which together are one instrument. Transmission by electronic means of and electronic form of a duly executed counterpart shall be deemed to constitute due and sufficient delivery of such counterpart and will be accepted and will be binding on the Parties whether or not subsequently replaced by originally signed duplicates.

10.11 Law and jurisdiction. This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) is governed by and construed in accordance with the laws of England irrespective of any conflicts of law principles. The Parties submit to the exclusive jurisdiction of the English courts in respect of any dispute arising out of or relating to this Agreement (including non-contractual disputes or claims) except that a Party may bring urgent or interim proceedings in any court of competent jurisdiction.

THIS AGREEMENT has been entered into and executed by the Parties as of the Effective Date.

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [*] INDICATES THAT INFORMATION HAS BEEN REDACTED.

Agreed by the Parties through their authorized signatories:

For and on behalf of **KODE Biotech Limited**:	For and on behalf of **Agalimmune Ltd.**:
/s/ Stephen Henry	/s/ Philip Serlin
Signed	Signed
Stephen Henry	Philip Serlin
Print name	Print name
CEO	Chairman of the Board
Job title	Job title
28 March 2018	28 March 2018
Date	Date
	Signed
	Print name
	Job title
	Date

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [*] INDICATES THAT INFORMATION HAS BEEN REDACTED.

Schedule 1

PART 1

Licensed Patents

KBL ref	Title	Filing date	CC	Application no. (patent no.)	Priority document(s)	Status
[*]	[*]	[*]	[*]	[*]	[*] [*] [*] [*] [*]	[*]
[*]	[*]	[*]	[*]	[*]	[*] [*] [*] [*] [*]	[*]
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Certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. [*] indicates that information has been redacted.

CONFIDENTIAL

[*]	[*]	[*]	[*]	[*]	[*] [*] [*] [*] [*]	[*]
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CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [*] INDICATES THAT INFORMATION HAS BEEN REDACTED.

Schedule 1

PART 2

Agalimmune Patent

KBL ref	Title	Filing date	CC	Application no. (Patent no.)	Priority document(s)	Status
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]

[*]

Exhibit 4.23

Certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. [*] indicates that information has been redacted.

SECOND AMENDMENT AGREEMENT

This Amendment Agreement ("**Amendment Agreement**"), dated as of **October 16, 2018** (the "**Execution Date**"), is between the University of Massachusetts ("**University**"), a not-for-profit, public institution of higher education of the Commonwealth of Massachusetts, established by Chapter 75 of the Massachusetts General Laws, as represented by its Medical School (Worcester campus), and Agalimmune Ltd ("**Company**"), a private limited company incorporated in England & Wales (company registration number 08504603) with registered address at 1st Floor Thavies Inn House, 3-4 Holborn Road, London, EC1N 2HA, United Kingdom.

WHEREAS University and Company entered into an Exclusive License Agreement effective as of **April 30, 2013** and thereafter amended such agreement in a document dated **February 6, 2017** (the License Agreement as amended shall be referred to as the "**Agreement**").

AND WHEREAS University and Company wish to further amend the License Agreement, with effect from the Effective Date (as defined below).

THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, University and Company agree as follows:

1 Definitions

1.1 "Effective Date" shall mean March 20, 2017.

1.2 Terms defined in the Agreement (including by way of cross-reference), unless otherwise defined herein, have the same meaning herein as if set out in this Amendment Agreement.

2 Amendments to the Agreement.

2.1 Amendment of Section 3.1. Section 3.1(b) of the Agreement shall be and is hereby replaced as of the Effective Date in its entirety by the following:

3.1(b) Development of Licensed Products.

(i) Within [*] days of the Commencement Date, Company shall furnish University with a written business plan under which Company intends as of the Commencement Date to develop Licensed Products.

(ii) Within [*] days after the start of each calendar year, beginning on January 1, 2014 Company shall furnish University with a written report on progress during the prior year to develop and commercialize Licensed Products, including without limitation research and development, efforts to obtain regulatory approval, marketing, and sales figures. Company shall also include in the report a discussion of its intended development and commercialization efforts and sales projections for the current year.

(iii) During [*], Company, its Affiliate or Sublicensee shall commence a Phase I clinical trial or its equivalent covering at least one (1) Licensed Product.

(iv) During [*], Company, its Affiliate or Sublicensee shall commence a Phase II clinical trial or its equivalent covering at least one (1) Licensed Product, should such a trial be required by the FDA.

(v) During [*], Company, its Affiliate or Sublicensee shall commence a Phase III clinical trial or its equivalent covering at least one (1) Licensed Product.

(vi) No later than [*], Company, its Affiliate or Sublicensee shall be ready to file a New Drug Application ("NDA") or Biologics License Application ("BLA") with the FDA covering at least one (1) Licensed Product.

(vii) Within [*] months after receiving FDA approval of the NDA or BLA for any Licensed Product, Company, its Affiliate or Sublicensee shall market the approved Licensed Product in the United States.

3 Miscellaneous

3.1 Binding Effect. This Amendment Agreement is binding upon and inures to the benefit of the parties and their respective permitted successors and assigns and are not intended to benefit, or be enforceable by, anyone else.

3.2 Assignment. This Amendment Agreement may not be assigned by either party without the prior written consent of the other party, which consent may not be unreasonably withheld or delayed. Notwithstanding the foregoing, this Amendment Agreement may be assigned by either party in connection with a merger, consolidation, sale of all of the equity interests of the party, or a sale of all or substantially all of the assets of the party to which this Amendment Agreement relates.

3.3 Amendment and Waiver. The parties may only amend, supplement, or otherwise modify this Amendment Agreement through a written instrument signed by both parties. The waiver of any rights or failure to act in a specific instance relates only to that instance and is not an agreement to waive any rights or fail to act in any other instance.

3.4 Governing Law. This Amendment Agreement is governed by and construed in accordance with the laws of the Commonwealth of Massachusetts irrespective of any conflicts of law principles. The parties may only bring legal action that arises out of or in connection with this Amendment Agreement in the Massachusetts Superior Court in Suffolk County.

3.5 Severability. If any provision of this Amendment Agreement is held invalid or unenforceable for any reason, the invalidity or unenforceability does not affect any other provision of this Amendment Agreement, and the parties shall negotiate in good faith to modify the Agreement to preserve (to the extent possible) their original intent. If the parties fail to reach a modified agreement within sixty (60) days after the relevant provision is held invalid or unenforceable, then the dispute shall be resolved in accordance with the procedures set forth in Article 9 of the Agreement. While the dispute is pending resolution, this Amendment Agreement shall be construed as if the provision were deleted by agreement of the parties.

3.6 Counterparts. This Amendment Agreement may be executed in one or more counterparts, each of which is an original, and all of which together are one instrument. A copy of an executed counterpart may be delivered by facsimile or other electronic means and such counterpart so delivered shall be equally effective for all purposes.

3.7 Entire Agreement. This Amendment Agreement constitutes the entire agreement between the parties with respect to its subject matter and supersedes all prior agreements or understandings between the parties relating to its subject matter.

THE PARTIES have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

UNIVERSITY OF MASSACHUSETTS

By: /s/ James P. McNamara
Name: James P. McNamara, Ph.D.,
Title: Executive Director
Office of Technology Management

AGALIMMUNE LTD.

By: /s/ Mali Zeevi
Name: Mali Zeevi
Title: Chief Financial Officer

Exhibit 4.24

Certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. [*] indicates that information has been redacted.

AMENDMENT NO. 1 TO LICENSE AGREEMENT

THIS AMENDMENT NO. 1 ("**Amendment**") is entered into effective as of June 18th, 2018 (the "**Amendment Effective Date**") by and between **BioLineRx Ltd**. ("**BioLine**") and **Wartner Europe BV** ("**Perrigo**").

PREFACE:

A. BioLine and Perrigo entered into a License Agreement dated as of December 22, 2014 (the "**Agreement**").

B. The Parties now wish to amend certain provisions of the Agreement.

NOW THEREFORE, the Parties hereby agree as follows:

1. Section 3.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

3.1 a. With respect to the Licensed Products referred to in Section 7.2, in consideration for the exclusive license granted to Licensee under Section 2.1, for each Licensed Product unit sold by Licensee and its Sublicensees in a given calendar quarter, Licensee will pay Licensor an amount equal to [*].

b. For the purpose of this Agreement, [*].

2. Subsections (a) and (b) of Section 3.2 are hereby deleted in their entirety and replaced with the following: [*]

3. Section 3.3 is hereby deleted in its entirety and not replaced.

4. (a) In Section 4.1, the sentence "Licensor has the right to examine Records that were created within five (5) years of the date of Licensor's request" is hereby amended to read "Licensor has the right to examine Records that were created within seven (7) years of the date of Licensor's request."

(b) In Section 4.2, the reference to "five (5) years" in the second line is hereby amended to "seven (7) years."

5. In Section 7.2(a), [*]

6. Following the Amendment Effective Date, if Perrigo desires to add one or more countries to the Territory, it shall notify BioLine of such desire, and the Parties shall negotiate in good faith as to whether and on what terms such country(ies) will be added to the Territory.

7. Capitalized terms used but not defined herein shall have the meanings set out in the Agreement. Except as otherwise specifically agreed in this Amendment, the existing terms of the Agreement shall remain in full force and effect.

8. This Amendment shall be binding upon the parties once executed by all parties and shall enter into force and become effective as of the Amendment Effective Date first written above.

[*signature page follows*]

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized representatives as of the Amendment Effective Date.

BioLineRx Ltd.	**Wartner Europe BV**
By: /s/ Philip Serlin	By: /s/ Christophe Van Damme
Name: Philip Serlin	Name: Christophe Van Damme
Title: Chief Executive Officer	Title: Director

Exhibit 8.1

Subsidiaries of BioLineRx Ltd.

The following table sets forth the name and jurisdiction of incorporation of our subsidiaries

Name of Subsidiary	Jurisdiction of Incorporation
Agalimmune Ltd.	England and Wales
BioLineRx USA Inc.	Delaware

Exhibit 12.1

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

I, Philip A. Serlin, certify that:

1. I have reviewed this annual report on Form 20-F of BioLineRx 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:

   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;

   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;

   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

   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):

   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

   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 16, 2022

/s/ Philip A. Serlin
Philip A. Serlin
Chief Executive Officer

Exhibit 12.2

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

I, Mali Zeevi, certify that:

1. I have reviewed this annual report on Form 20-F of BioLineRx 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:

   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;

   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;

   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

   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):

   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

   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 16, 2022

/s/ Mali Zeevi
Mali Zeevi
Chief Financial Officer

Exhibit 13.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 906 OF
THE SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of BioLineRx Ltd. (the "Company") hereby certifies to such officer's knowledge that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2021 (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

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2022

/s/ Philip A. Serlin
Philip A. Serlin
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

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of BioLineRx Ltd. (the "Company") hereby certifies to such officer's knowledge that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2021 (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

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2022

/s/ Mali Zeevi
Mali Zeevi
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 hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-176419, 333-183976, 333-201326 and 333-208865) and Form F-3 (No. 333-251857 and 333-229021) of BioLineRx Ltd. of our report dated March 15, 2022 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

Tel-Aviv, Israel
March 15, 2022

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited