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, 2023

OR

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

OR

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

Date of event requiring this shell company report

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
+972 (8) 642-9100
+972 (8) 642-9101 (facsimile)
phils@biolinerx.com
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, 2023: 1,086,589,165 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. ☒

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

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

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

U.S. GAAP ☐	International 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 include statements regarding management's expectations, beliefs and intentions regarding, among other things, the potential benefits of APHEXDA, the ongoing commercialization of APHEXDA and the plans and objectives of management for future operations and expectations and commercial potential of APHEXDA, as well as its potential investigational uses. 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 clinical development, commercialization and market acceptance of our therapeutic candidates, including the degree and pace of market uptake of APHEXDA for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients;
- 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;
- whether the clinical trial results for APHEXDA will be predictive of real-world results;
- our receipt of regulatory approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- whether access to APHEXDA is achieved in a commercially viable manner and whether APHEXDA receives adequate reimbursement from third-party payors;
- our ability to establish, manage, and maintain corporate collaborations, as well as the ability of our collaborators to execute on their development and commercialization plans;
- our ability to integrate new therapeutic candidates and new personnel, as well as new collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model and strategic plans for our business and therapeutic candidates;
- the scope of protection that 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 need for and ability to access sufficient additional financing, including any unexpected costs or delays in the ongoing commercialization of APHEXDA;
- 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, including the impact of Israel's war with Hamas and other militant groups, which may exacerbate the magnitude of the factors discussed above; and
- those factors referred to in "Item 3.D. Risk Factors," "Item 4. Information on the Company," and "Item 5. Operating and Financial Review and Prospects", as well as in this annual report on Form 20-F generally.

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 have incurred significant losses since inception and 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.
- If we default under our secured loan agreement with Kreos, all or a portion of our assets could be subject to forfeiture.

Risks Related to Our Business and Regulatory Matters

- We have only recently transitioned from a development stage biopharmaceutical company to a commercial stage biopharmaceutical company, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- APHEXDA has been launched in the United States and there is significant competition in this marketplace. Since this is our first independently marketed therapeutic, the timing of uptake and distribution efforts are unpredictable and there is a risk that we may not achieve and sustain commercial success for APHEXDA.
- APHEXDA, or any other therapeutic candidate that may receive marketing approval in the future, may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for APHEXDA or any other therapeutic candidate may be smaller than our estimates.
- If we or our collaborators are unable to obtain and/or maintain U.S. and/or foreign regulatory approval for our therapeutic candidates, in a timely manner or at all, we will be unable to commercialize our therapeutic candidates.
- We may not obtain additional marketing approvals for motixafortide in other indications or initial approval for any other therapeutic candidates we may develop in the future.

- 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 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 have in the past and may depend in the future 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.
- We have partnered with and may 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 therapeutic candidates successfully, if at all.
- If our competitors develop and market therapeutics that are more effective, safer or less expensive than our current or future therapeutic candidates, our prospects will be negatively impacted.
- APHEXDA, or any other therapeutic candidate that we or our collaborators are able to commercialize, may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives, any of which could harm our business.
- We rely upon third-party manufacturers to produce therapeutic supplies for the clinical trials, and commercialization, of APHEXDA. If we manufacture any therapeutic candidates in the future, we will be required to incur significant costs and devote significant efforts to establish and maintain manufacturing capabilities.

Risks Related to Our Industry

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

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.

Risks Related to our Ordinary Shares and ADSs

- Our business, operating results and growth rates may be adversely affected by current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk.
- 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 a substantial part of our operations in Israel and therefore our results may be adversely affected by political, economic and military instability in Israel and its region.
- 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 have incurred significant losses since inception and expect to incur additional losses in the future and may never be profitable.

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 and more recently sales and marketing in support of our operations. We recorded net losses of $27.1 million in 2021, $25.0 million in 2022 and $60.6 million in 2023. As of December 31, 2023, we had an accumulated deficit of $391 million. We expect to continue to incur significant expenses and sustain net losses for the foreseeable future as we commercialize APHEXDA in stem cell mobilization for autologous bone marrow transplantation in multiple myeloma patients in the United States and continue our planned development activities for motixafortide in other indications.

Our ability to become and remain profitable depends on our ability to generate significant product revenue. Our ability to generate significant revenue will require us to successfully commercialize APHEXDA. While we began to generate product revenue from sales of APHEXDA, there can be no assurance that we will generate significant revenue or as to the timing of any such revenue, and we may not achieve profitability for several years, if at all. Successful commercialization is subject to many risks. There are numerous examples of unsuccessful product launches and failures to meet expectations of market potential, including by pharmaceutical companies with more experience and resources than us.

Successful commercialization will depend upon our ability to achieve sufficient market acceptance, reimbursement from third-party payers and adequate market share for APHEXDA. The likelihood of our long-term success must be considered in light of the expenses, difficulties and potential delays to be encountered in the development and commercialization of new pharmaceutical products, competitive factors in the marketplace and the complex regulatory environment in which we operate. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any collaborators may never succeed in these activities and, even if we do, or any collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline or continue our operations. A decline in the value of our company could cause our shareholders to lose all or part of their investment.

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

As of December 31, 2023, we held $43.0 million of cash, cash equivalents and short-term bank deposits. Based on our current projected cash requirements, we believe that our existing cash and investment balances and other sources of liquidity, including net product revenues from product sales of APHEXDA and milestone payments from the License Agreement (as defined below), will be sufficient to meet our capital requirements into 2025. 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 costs of commercializing APHEXDA, 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 commercialization in the United States for APHEXDA, 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.

If we default under our secured loan agreement with Kreos, all or a portion of our assets could be subject to forfeiture.

In September 2022, we entered into a secured loan agreement, or the Loan Agreement, with Kreos Capital VII Aggregator SCSP, or Kreos VII and together with Kreos V, Kreos Capital. Under the Loan Agreement, Kreos Capital will provide the Company with access to term loans in an aggregate principal amount of up to $40 million in three tranches as follows: (a) a loan in the aggregate principal amount of up to $10 million, (b) a loan in the aggregate principal amount of up to $20 million, available for drawdown upon achievement of certain milestones and until April 1, 2024, and (c) a loan in the aggregate principal amount of up to $10 million, available for drawdown upon achievement of certain milestones and until October 1, 2024. We drew down the initial tranche of $10 million following execution of the agreement in September 2022.

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 agreements. If we default on the Loan Agreement and are unable to cure the default pursuant to the terms of the Loan Agreement or are unable to repay or refinance the loan when due, Kreos could take possession of any or all assets in which it holds a security interest, and dispose those assets to the extent necessary to pay off the debts, which would have a material adverse effect on our business, financial condition, prospects or results of operations.

Risks Related to Our Business and Regulatory Matters

We have only recently transitioned from a clinical development biopharmaceutical company to a commercial stage biopharmaceutical company, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We only recently launched APHEXDA in the U.S. following FDA approval in September 2023. Until then we were considered a clinical development biopharmaceutical company. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had more experience commercializing APHEXDA. To be profitable, we will need to successfully transition from a company with a research and development focus to a company capable of supporting commercial activities. Ultimately, we may not be successful in such a transition.

APHEXDA has been launched in the United States and there is significant competition in this marketplace. The timing of uptake and distribution efforts are unpredictable and there is a risk that we may not achieve and sustain commercial success for APHEXDA.

We are currently executing on an independent commercialization plan for APHEXDA in stem cell mobilization for autologous bone marrow transplantation in multiple myeloma patients in the U.S. We have established sales, marketing and distribution capabilities and are commercializing APHEXDA in the U.S. Successful commercialization of APHEXDA in the U.S. or elsewhere will require significant resources and time and, while our personnel are experienced with respect to marketing of healthcare products, the potential uptake of the product in distribution and the timing for growth in sales, if any, is unpredictable and we may not be successful in commercializing APHEXDA in the long term. In particular, successful commercialization of APHEXDA will require that we enter into and maintain contractual relationships with specialty distributors that supply to the transplantation centers and we are able to overcome competition from the established standard of care product and its generic versions, where average selling price reimbursement is currently favoring the generic market.

During 2023, we recruited an in-house field sales team. Before then we had not previously employed an in-house field sales team, and thus, although we hired a very experienced head of our U.S. commercial operations, we have limited experience in overseeing and managing an employed sales force. We expect that it will take time for this team to generate significant sales momentum, if it does so at all. In addition, retention of capable sales personnel may be more difficult as we focus on a single product offering and we must retain our sales force in order for APHEXDA to establish a commercial presence.

In addition, other factors that have and may continue to inhibit our efforts to successfully commercialize APHEXDA include our ability to access key health care decision makers, price APHEXDA at a sufficient price point to ensure an adequate and attractive level of profitability, and maintain sufficient financial resources to cover the costs and expenses associated with creating and sustaining a capable sales and marketing organization and related commercial infrastructure.

If we are not successful, we may be required to collaborate or partner APHEXDA with a third-party pharmaceutical or biotechnology company with existing products. To the extent we collaborate or partner, the financial value will be shared with another party and we will need to establish and maintain a successful collaboration arrangement, and we may not be able to enter into these arrangements on acceptable terms or in a timely manner in order to establish APHEXDA in the market. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In that event, our product revenues may be lower than if we marketed and sold our products directly with the highest priority, and we may be required to reduce or eliminate much of our commercial infrastructure and personnel as a result of such collaboration or partnership.

If we are not successful in setting our marketing, pricing and reimbursement strategies, recruiting and maintaining effective sales and marketing personnel or building and maintaining the infrastructure to support commercial operations in the U.S. and elsewhere, we will have difficulty successfully commercializing APHEXDA, which would adversely affect our business and financial condition.

APHEXDA, or any other therapeutic candidate that may receive marketing approval in the future, may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for APHEXDA or any other therapeutic candidate may be smaller than our estimates.

APHEXDA, or any other therapeutic candidate that may be approved in the future by the appropriate regulatory authorities for marketing and sale, may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. APHEXDA competes with the standard of care for stem cell mobilization and its generic versions.

Efforts to educate the medical community and third-party payors on the benefits of APHEXDA over its competition have required significant resources and may not ultimately be successful. If APHEXDA, or any other therapeutic candidate that may be approved in the future for marketing and sale in the future, does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of APHEXDA, or any other therapeutic candidate that may be approved in the future, will depend on a number of factors, including:

- the advantages of the treatment compared to competitive therapies;
- the number of competitors approved for similar uses;
- the relative promotional effort and marketing success of us as compared with our competitors;
- how the product is positioned in physician treatment guidelines and pathways;
- the prevalence and severity of any side effects;
- the efficacy and safety of the product;
- our ability to offer the product for sale at competitive prices;
- the product's tolerability, convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including use restrictions, contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- the timing of market introduction of our approved products as well as competitive products;
- adverse publicity about the product or favorable publicity about competitive products;
- potential product liability claims;
- changes in the standard of care for the targeted indications of the product; and
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

In addition, the potential market opportunities for APHEXDA and any other therapeutic are difficult to estimate precisely. Our estimates of the potential market opportunities are predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions prove to be inaccurate, the actual markets for our therapeutic candidate could be smaller than our estimates of the potential market opportunities.

If the commercial launch of APHEXDA for which we recruited a sales force and established marketing, market access and medical affairs teams and distribution capabilities is not successful for any reason, we could incur substantial costs and our investment would be lost if we cannot retain or reassign our sales, marketing, market access and medical affairs personnel.

To achieve commercial success for APHEXDA, we have expended and anticipate that we will continue to expend significant resources to support our sales force, marketing, market access and medical affairs teams and distribution capabilities. There are risks involved with establishing our own sales, marketing, distribution, training and support capabilities. For example, recruiting and training sales and marketing personnel is expensive and time consuming and could delay our ability to focus on other priorities. If the commercial launch of APHEXDA is not successful for any reason, this would be costly, and our investment would be lost if we cannot retain or reassign our sales, marketing, market access and medical affairs personnel or terminate on favorable terms any agreements entered into with third parties to support our commercialization efforts.

Factors that may inhibit or limit our efforts to commercialize APHEXDA on our own include:

- our inability to train and retain adequate numbers of effective sales, marketing, training and support personnel;
- the inability of sales personnel to obtain access to physicians, including key opinion leaders, or to educate an adequate number of physicians of the benefits of APHEXDA over alternative treatment options; and
- unforeseen costs and expenses associated with establishing and maintaining an independent sales, marketing, training and support organization.

If our sales force, marketing, market access and medical affairs teams and distribution capabilities fail, or are otherwise unsuccessful, it would materially adversely impact the commercialization of APHEXDA, impact our ability to generate revenue and harm our business.

Even if a therapeutic candidate receives marketing approval, we or others may later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise our ability or that of any collaborators to market the product, and could cause regulatory authorities to take certain regulatory actions.

It is possible that our clinical trials may indicate an apparent positive effect of a therapeutic candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. For example, despite the recent FDA marketing approval of APHEXDA in the United States, we, or others, may discover that APHEXDA is less effective or tolerable than previously believed. If, we, or others, discover that a product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or any of our collaborators, may be required to recall the product, change the way the product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- we, or any of our collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we, or any of our collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- physicians and patients may stop using our product; and
- our reputation may suffer.

Any of these events could harm our business and operations and could negatively impact the market price of our ordinary shares and/or ADSs.

If we or our collaborators are unable to obtain and/or maintain U.S. and/or foreign regulatory approval for our therapeutic candidates in a timely manner or at all, we will be unable to commercialize our therapeutic candidates.

Although the commercialization of APHEXDA in stem cell mobilization for autologous bone marrow transplantation in multiple myeloma patients in the U.S. is our primary focus, we continue to develop motixafortide in other geographies and indications. Motixafortide and any other therapeutic candidate we develop will require additional, time-consuming and costly development efforts, by us or by our collaborators, prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable foreign regulatory authorities. All therapeutic candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the therapeutic candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace, or will be more effective than other commercially available alternatives.

In the United States, we are required to submit a New Drug Application, or NDA, to obtain FDA approval before marketing any of our current or future 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 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. The FDA may require that we conduct additional clinical or preclinical trials, or take other actions before it will approve or reconsider any application we make. 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.

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 collaborators, 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.

We may not obtain additional marketing approvals for motixafortide in other indications or initial approval for any other therapeutic candidates we may develop in the future.

We may not obtain additional marketing approvals for motixafortide or any other therapeutic candidate that we may develop in the future. It is possible that the FDA or comparable foreign regulatory agencies may refuse to accept for substantive review any future application that we or a collaborator may submit to market and sell our therapeutic candidates, or that any such agency may conclude after review of our or our collaborator's data that such application is insufficient to obtain marketing approval of our therapeutic candidate.

If the FDA or other comparable foreign regulatory agency does not accept or approve any future application to market and sell any therapeutic candidate, such regulators may require that we conduct additional clinical trials, preclinical studies or manufacturing validation studies and submit that data before they will reconsider our application. Depending on the extent of these or any other required trials or studies, approval of any application that we submit may be delayed by several years, or may require us or our collaborator to expend more resources than we or they have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the FDA or other foreign regulatory agency to approve our applications for marketing and commercialization.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us or our collaborators from commercializing motixafortide in other jurisdictions and indications or any other therapeutic candidate that we may develop in the future and generating revenues. If any of these outcomes occur, we would not be eligible for certain milestone and royalty revenue under our partnership agreements, our collaborators could terminate our partnership agreements and we may be forced to abandon our development efforts, any of which could significantly harm our business.

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.

Clinical trials are expensive and complex, can take many years and have uncertain outcomes. We cannot necessarily predict whether we or any licensee will encounter problems with any of the completed, ongoing or planned clinical trials that will cause us, any licensee 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 certain of our clinical trials 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 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 any therapeutic candidate. For example, we previously investigated the treatment of motixafortide for acute myeloid leukemia, AML, and following an interim analysis of a Phase 2b trial in which the investigational arm of motixafortide combined with cytarabine did not demonstrate a statistically significant effect in the study's primary endpoint, we terminated the study. Nevertheless, 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. 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, motixafortide and any other therapeutic candidate that we may develop in the future 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 therapeutics we or any licensee develops receive regulatory approval, we or any licensee, as applicable, will be subject to ongoing reporting obligations, and any approved products and the manufacturing operations for such products 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 a drug product following its 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 any licensee, supplier, third-party contractor, partner or clinical investigator is 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 any licensee 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 motixafortide, and we rely on third parties, such as contract laboratories, contract research organizations, medical institutions, clinical investigators and other collaborators to conduct these studies and clinical trials. Our reliance on these third parties limits our control over these activities. The collaborators 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 collaborators 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-parties 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, motixafortide and any other therapeutic candidate that we may develop in the future may be delayed. The collaborators may also have relationships with other commercial entities, some of whom may compete with us. If the collaborators 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 have in the past and may in the future rely on out-licensing arrangements for late-stage development, marketing and commercialization.

Although we are executing on an independent commercialization plan for APHEXDA in stem cell mobilization for autologous bone marrow transplantation in multiple myeloma patients, we have in the past and may in the future rely on out-licensing arrangements for late-stage development, marketing and commercialization. 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 a licensee devotes to our therapeutic candidate;
- a licensee may experience financial difficulties;

- a licensee may fail to secure adequate commercial supplies of our therapeutic candidate upon marketing approval, if at all;
- our future revenues depend heavily on the efforts of a licensee;
- 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 licensee breaches or terminates its agreement with us, or if any licensee otherwise fails to conduct its 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. Our dependence on a licensee's experience and the rights of a licensee will limit our flexibility in considering alternative out-licensing arrangements for any therapeutic candidate. Any failure to successfully develop these arrangements or failure by a licensee to successfully develop or commercialize any therapeutic candidate in a competitive and timely manner will have a material adverse effect on the commercialization of any therapeutic candidate.

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. For example, we recently determined to terminate development of AGI-134 and provided notice of our intent to terminate the Agalimmune Development Agreement effective March 15, 2024.

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 any of 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; and from Innovative Pharmaceutical Concepts, Inc., or IPC, with respect to our BL-5010 therapeutic candidate. See "Item 4.B. 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. Due to the relatively advanced stage of development of the compound licensed from Biokine, in the case of self-commercialization, our license agreement with Biokine provides for royalty payments of 10% of net sales, subject to certain limitations. In addition, Biokine is entitled to a monthly fee until March 2029. 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.

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

Although we are currently executing on an independent commercialization plan for APHEXDA in stem cell mobilization for autologous bone marrow transplantation in multiple myeloma patients, we collaborate with third parties with respect to the development of motixafortide in other indications and may in the future seek a partner for any other therapeutic candidate. In August 2023, we entered into a license agreement pursuant to which we granted an exclusive, royalty-bearing, sublicensable license with respect to the intellectual property rights and know-how associated with motixafortide in order to develop and commercialize motixafortide in Asia (other than Israel and certain other countries). See "Item 4.B. Information on the Company—Business Overview—Our Product Pipeline—Out licensing of Motixafortide in Asia". We may compete with many other companies if we seek additional 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 additional collaboration arrangements for motixafortide and for any other therapeutic candidate, we would be required to undertake and fund further development, clinical trials, manufacturing and commercialization activities solely at our own expense and risk, as is the case with motixafortide in stem cell mobilization for autologous bone marrow transplantation in multiple myeloma patients in the U.S. 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 therapeutic 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 may in the future 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 therapeutic candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

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 motixafortide 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, solid malignancies and skin lesions. In particular, during 2023, the last to expire patent for Mozobil and uses thereof, the standard of care for stem cell mobilization, expired and as a consequence there are several generic versions on the market. Successful commercialization of APHEXDA will in part require that we are able to overcome competition from Mozobil and its generic versions, where average selling price reimbursement is currently favoring the generic market.

Any therapeutic candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The key competitive factors affecting the success of each therapeutic candidate, if approved, is likely to be their safety, efficacy, convenience, price, the level of proprietary and generic competition, and the availability of coverage and reimbursement from government and other third-party payors. Our APHEXDA sales will suffer or our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, or are more convenient or less expensive than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their therapeutic candidates more rapidly than we may be able to do so for any existing or new therapeutic candidates of ours, which could result in their establishing a strong market position before we are able to enter the market.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in favor of our competitors. Additionally, many competitors have greater experience in product discovery and development, obtaining FDA and other regulatory approvals and commercialization capabilities, which may provide them with a competitive advantage. If we are not able to compete effectively, our business will not grow and our financial condition and operations will suffer.

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.

APHEXDA, or any other therapeutic candidate that we or our collaborators are able to commercialize, may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives, any of which could harm our business.

The commercial success of APHEXDA and any other therapeutic candidate will depend substantially, both domestically and abroad, on the extent to which product costs will be paid by third-party payors, including government health care programs and private health insurers. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our collaborators might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our or their investment in one or more therapeutic candidates, even if our therapeutic candidates obtain marketing approval.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any collaborators, to successfully commercialize any of our therapeutic candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell APHEXDA profitably. These payors may not view APHEXDA as cost-effective, and coverage and reimbursement may not be available to our customers or may not be sufficient to allow our products to be marketed on a competitive basis. Cost-control initiatives could cause us or our collaborators to decrease the price we might establish, which could result in lower than anticipated product revenues. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, such as APHEXDA, and coverage may be more limited for APHEXDA than for other drug products with similar indications approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any therapeutic will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, for example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost treatments or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that coverage will be available for any therapeutic candidate that we, or third-parties, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for products may be subject to additional reductions if there are changes to laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for therapeutic candidate for which we obtain regulatory approval could significantly harm our operating results and our overall financial condition.

We rely upon third-party manufacturers to produce therapeutic supplies for the clinical trials, and commercialization, of APHEXDA. If we manufacture any 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 or commercialization. We rely on third-party manufacturers to produce the therapeutic supplies that enable us to perform clinical trials and supply commercial scale product. We have limited personnel with experience in drug product manufacturing and we lack the resources and capabilities to manufacture any of our therapeutic candidates on a commercial scale. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products 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 product and we rely on single source suppliers. When we require additional supplies to complete our clinical trials or for commercialization, 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.

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.

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 cGMP, for drugs. 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 subject to prior notice as applicable. 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, since we are independently commercializing APHEXDA, 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.

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

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

Our business may be adversely affected if there is a resurgence of the COVID-19 pandemic.

The novel coronavirus outbreak, or COVID-19, has affected segments of the global economy. Due to clinical operating issues associated with the COVID-19 pandemic, during 2020, we temporarily suspended enrollment to the phase 1/2a study for AGI-134, our second lead compound. If there is a resurgence, COVID-19 could impact our future operations, including potential interruptions to supply chains, clinical trials, commercialization activities and regulatory reviews and approvals. Any resurgence of the COVID-19 pandemic 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 any resurgence of COVID-19 could materially affect our business and the value of our shares. Additionally, if a resurgence of 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 may be 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 in the past 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 any resurgence of COVID-19 or other pandemics 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 any resurgence of the COVID-19 and other pandemics and related restrictions and implications and the effectiveness of actions taken to contain and treat the diseases, all of which are uncertain and cannot be predicted. The impact of any resurgence of the COVID-19 pandemic or another 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.

Risks Related to Our Industry

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 ACA, and (ii) trends in the practices of managed care groups and institutional and governmental purchasers, including the impact of consolidation of our customers. In 2022, the IRA, established the Medicare Drug Price Negotiation Program which permits the government to negotiate "maximum fair" drug prices for certain high expenditure, single source drugs and biologics. It is estimated that over the next seven years, 60 drugs covered under Medicare B and D will have negotiated a "maximum fair price."

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 ACA 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, such as the IRA, 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. The IRA will modify 60 drugs and biologics through negotiation of a fair maximum pricing for CMS. 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. In addition, we have a cyber insurance policy with a coverage amount of $5.0 million per each claim and in the aggregate 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.

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

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

Risks Related to 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. 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. 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 any therapeutic candidate, 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, 2024, we owned or exclusively licensed for uses within our field of business 29 patent families that collectively contain 128 granted patents, 4 allowed patent applications and 73 pending patent applications relating to the three candidates listed below.

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 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, 2023 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 are a PFIC for the year ended December 31, 2023. Although we have not determined whether we will be a PFIC for our taxable year ending December 31, 2024, 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 2024 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, 2023, 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."

If a United States person is treated as owning at least 10% of our shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a United States person is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our shares, such person may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, whether or not we make any distributions, and may be subject to tax reporting obligations. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. A failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist any shareholder in determining whether such shareholder is treated as a United States shareholder with respect to any "controlled foreign corporation" in our group (if any) or furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax paying obligations. A United States investor should consult its tax advisors regarding the potential application of these rules to its investment in the shares.

Our business, operating results and growth rates may be adversely affected by current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk.

Our business depends on the economic health of the global economies. If the conditions in the global economies remain uncertain or continue to be volatile, or if they deteriorate, including as a result of the impact of military conflict, such as the war between Russia and Ukraine, terrorism or other geopolitical events, our business, operating results and financial condition may be materially adversely affected. Economic weakness, inflation and increases in interest rates, limited availability of credit, liquidity shortages and constrained capital spending have at times in the past resulted, and may in the future result, in challenging and delayed sales cycles, slower adoption of new technologies and increased price competition, and could negatively affect our ability to forecast future periods, which could result in an inability to satisfy demand for our products and a loss of market share.

In addition, increases in inflation raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with the uncertainties surrounding any resurgence of COVID-19, geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment, which may make it more difficult, costly or dilutive for us to secure additional financing. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows.

There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and market price of our ordinary shares and ADSs and could require us to alter our operating plans. In addition, there is a risk that one or more of our service providers, financial institutions, manufacturers, suppliers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

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 Tel Aviv Stock Exchange, or 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 — "*Our business, operating results and growth rates may be adversely affected by current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk.*"

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. Following periods of market volatility, shareholders have often instituted securities class action litigation and we are currently party to two purported securities class action litigation. See "Item 8.A—Financial Information—Legal Proceedings" for additional information. Such securities litigation or any additional securities litigation 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, 2024, 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 718,750 ADSs at an exercise price of $3.00 per ADS, (iii) for the purchase for the purchase of 11,090,910 ADSs at an exercise price of $1.15 per ADS and (iv) for the purchase of 681,818 ADSs at an exercise price of $1.375 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, 2024, we have sold 2,109,858 of our ADSs for total gross proceeds of approximately $4.4 million under the New HCW Offering Agreement.

As of March 15, 2024, in the framework of our Share Incentive Plan, there are outstanding options, restricted share units and performance share units (granted to directors, employees and consultants) for the purchase of 152,198,865 ordinary shares (equivalent to 10,146,591 ADSs) with a weighted average exercise price of $0.10 per ordinary share (equivalent to $1.47 per ADS).

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, in a timely manner or at all, 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 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 follow home country practice in Israel with regard to, among other things, director nomination procedure, 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 a substantial part of 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 and principal executive offices, development, and some of our suppliers and third-party contractors are located in central Israel. In addition, a number of our key employees, the majority of our officers and directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries, and between Israel and the Hamas (an Islamist militia and political group in the Gaza Strip) and Hezbollah (an Islamist militia and political group in Lebanon).

In particular, in October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on the Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in thousands of deaths and injuries, and Hamas additionally kidnapped many Israeli civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and commenced a military campaign against Hamas and these terrorist organizations in parallel continued rocket and terror attacks. As a result of the events of October 7, 2023 whereby Hamas terrorists invaded southern Israel and launched thousands of rockets in a widespread terrorist attack on Israel, the Israeli government declared that the country was at war and the Israeli military began to call-up reservists for active duty. None of our employees were called up for active duty; however military service call ups that result in absences of personnel from us for an extended period of time may materially and adversely affect our business, prospects, financial condition and results of operations. As of the date hereof, we currently have 69 full-time and 10 part-time employees, with 43 employees located in Israel and 36 employees located outside of Israel.

Since the war broke out on October 7, 2023, our operations have not been adversely affected by this situation, and we have not experienced disruptions to our clinical studies. We are the sponsor of just one clinical trial in Israel with one clinical site. Our commercial operations including the manufacturing operations and supply of APHEXDA take place in the United States and therefore remain unaffected by the war against Hamas. However, the intensity and duration of Israel's current war against Hamas is difficult to predict at this stage, as are such war's economic implications on the Company's business and operations and on Israel's economy in general. If the war extends for a long period of time or expands to other fronts, such as Lebanon, Syria and the West Bank, our operations may be adversely affected.

In addition, since the commencement of these events, there have been continued hostilities along Israel's northern border with Lebanon (with the Hezbollah terror organization) and southern border (with the Houthi movement in Yemen). It is possible that hostilities with Hezbollah in Lebanon will escalate, and that other terrorist organizations, including Palestinian military organizations in the West Bank as well as other hostile countries, such as Iran, will join the hostilities. Such clashes may escalate in the future into a greater regional conflict. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, the Houthi movement in Yemen and various rebel militia groups in Syria. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions, could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business may decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. 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 such agreements. Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. 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. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations.

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

Finally, political conditions within Israel may affect our operations. Israel has held five general elections between 2019 and 2022, and prior to October 2023, the Israeli government pursued extensive changes to Israel's judicial system, which sparked extensive political debate and unrest. To date, these initiatives have been substantially put on hold. Actual or perceived political instability in Israel or any negative changes in the political environment, may individually or in the aggregate adversely affect the Israeli economy and, in turn, our business, financial condition, results of operations and growth prospects.

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, which obligate us to pay certain royalties on our revenues to the Israeli government. The terms of these grants may require us to satisfy specified conditions in order to transfer the manufacture of products and technologies outside of Israel and to make additional payments 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 Encouragement of Industrial Research, Development and Technological Innovation Law, 1984, and related regulations, as amended, or the Research Law, with respect to these projects. Through December 31, 2023, we had received approximately $22.0 million in funding from the IIA and paid the IIA approximately $7.6 million in royalties under our approved programs. As of December 31, 2023, we had 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 in connection with our in-licensing of motixafortide (which liability has no relation to the IIA funding actually received by us) amounted to $3.2 million as of December 31, 2023. We have a full right of offset for amounts payable to the IIA for motixafortide from payments that we may owe to Biokine in the future.

The transfer or licensing to third parties outside of Israel of know-how or technologies developed under the IIA funded programs and derivatives thereof, or the transfer to third parties outside of Israel of manufacturing or rights to manufacture based on and/or incorporating such IIA funded know-how, requires, in certain circumstances, 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 IIA funded 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 the transfer or licensing of manufacturing rights or other know-how or assets outside of Israel that might otherwise be beneficial to us. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of Israel of technology or know-how developed with IIA funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the IIA. See Item 4.B. — Information on the Company — Business Overview - Israeli Government Programs — *Israel Innovation Authority*."

Even following the full repayment of any IIA grants, we must nevertheless continue to comply with the requirements of the Research Law. If we fail to comply with any of the conditions and restrictions imposed by the Research Law and regulations and guidelines thereunder, or by the specific terms under which we received the grants, we may be required to refund any IIA grants previously received together with interest and penalties, and, in certain circumstances, may be subject to criminal charges.

Provisions of Israeli law and our Articles of Association 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 tender offer for all of a company's issued and outstanding shares 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). Furthermore, the shareholders, including those who indicated their acceptance of such a 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 an Israeli court to alter the consideration for the acquisition accordingly (unless the acquirer stipulated in its 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, such as for those 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, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restriction. 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.

Further, our Articles of Association, as amended at our annual general meeting of shareholder held in August 2023, provide that our directors (other than external directors, if any) are elected on a staggered basis, such that a potential acquirer cannot readily replace our entire board of directors at a single annual general shareholder meeting; rather, at least two annual meetings of shareholders will generally be required to effect a change in a majority of our board of directors.

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.

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

We are incorporated in Israel. Most of our executive officers and the majority of our directors reside outside of the United States, and a significant portion of our assets and most of the assets of such 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 a judgment 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. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above.

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, as well as a general duty to refrain from discriminating against other shareholders. 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 nature of these duties or the implications of these provisions. 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. Our wholly owned subsidiary, BioLineRx USA, Inc., was incorporated in Delaware on January 4, 2008, and is located at 77 Fourth Ave, Waltham, Massachusetts 02451, and its telephone number is (617) 859-6409.

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.

Our capital expenditures for the year ended December 31, 2021 were immaterial and were $0.3 million for each of the years ended December 31, 2022 and 2023. 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 commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases. Our primary commercialization pipeline consists of APHEXDA (motixafortide), a novel peptide for the treatment of stem-cell mobilization and solid tumors, which, on September 8, 2023, was approved by the FDA for use in combination with G-CSF, also known as filgrastim, to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma. We are also advancing the development of motixafortide for patients with sickle cell disease and pancreatic cancer. In addition, we have an off-strategy, legacy therapeutic product called BL-5010 for the treatment of skin lesions.

We seek to develop and commercialize 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. 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. Our strategy includes commercializing our therapeutic candidates by way of out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case-by-case basis, the commercialization of our therapeutic candidates independently. In this regard, we are currently executing on an independent commercialization plan for APHEXDA in stem cell mobilization for autologous bone marrow transplantation in multiple myeloma patients.

With headquarters and development operations in Israel, and commercialization operations in the U.S., we are driving innovative therapeutics with end-to-end expertise in development and commercialization, ensuring life-changing discoveries move beyond the bench to the bedside.

We use “APHEXDA” when referring to our FDA approved drug and “motixafortide” when referring to our development of APHEXDA for additional indications.

FDA Approval and U.S. Launch of APHEXDA

In September 2023, the FDA approved motixafortide in combination with G-CSF to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma. Following this approval, we commenced commercialization of motixafortide in the U.S. independently, as planned, in order to accelerate its availability to patients and to maximize the value of this innovative therapeutic candidate.

The FDA approval of APHEXDA is based on results from the 2-part, Phase 3 GENESIS trial, a randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of APHEXDA plus G-CSF compared to placebo plus G-CSF, for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients. Top-line results announced in 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.

During 2023, we completed the build-out of the infrastructure for commercial operations in the U.S. designed to support the commercialization of APHEXDA. In addition, we completed the onboarding of customer-facing personnel on our sales, medical affairs, and national accounts teams, which have engaged with transplant centers, physicians, and payers. Patient-focused support has also been critical to our launch efforts with the creation of BioLineRx Connect, our internal patient support program, as well as the establishment of relationships with patient advocacy groups.

Our focus has been on the top 80 centers that perform 85% of the autologous stem cell transplantations, or ASCTs, in multiple myeloma in order to build the foundations for commercial expansion. Among this defined population, we have been granted formulary status for APHEXDA at hospitals representing approximately 20% of the total annual U.S. multiple myeloma transplant procedures at these centers and expect this number to grow as additional formulary reviews are scheduled. In addition, we have received inclusion of APHEXDA in the National Comprehensive Cancer Network (NCCN) guidelines for Hematopoietic Cell Transplantation Importantly, we have achieved positive coverage decisions by payers representing 95% of all covered lives in the U.S. and received Healthcare Common Procedure Coding System (HCPCS) J-Code to facilitate Medicare reimbursement for APHEXDA to transplant centers treating Medicare beneficiaries.

Out Licensing of Motixafortide in Asia

On August 27, 2023, we entered into a License Agreement, or the License Agreement, with Hong Seng Technology Limited, or HST, and Guangzhou Gloria Biosciences Co., Ltd., or Gloria, and/or with HST, the Licensee, pursuant to which we granted HST an exclusive, royalty-bearing, sublicensable license with respect to the intellectual property rights and know-how associated with motixafortide in order to develop and commercialize motixafortide in Asia (other than Israel and certain other countries), or the Territory, and to engage and authorize Gloria to perform services under the License Agreement in the Territory.

Pursuant to the terms of the License Agreement, the Licensee made a $15 million upfront payment in October 2023, upon the closing of the transaction. We are entitled to up to $49 million based on the achievement of certain development and regulatory milestones in China and Japan, and up to $197 million in sales milestones based on defined sales targets of motixafortide in the Territory. Additionally, we are eligible to receive tiered, double-digit royalties (ranging from 10-20%), on aggregate net sales of motixafortide in the Territory payable on a country-by-country basis until the longer of (i) fifteen years from the date of the first sale of motixafortide by Licensee, (ii) the last to expire valid claim of any licensed patents with respect to motixafortide in such country and (iii) the expiration of motixafortide's orphan drug status in such country. The royalties payable by Licensee to us are to be reduced by 50% following the end of the initial royalty term and to also be reduced upon the occurrence of certain events, including, on a country-by-country basis, the entry of a generic product in such country.

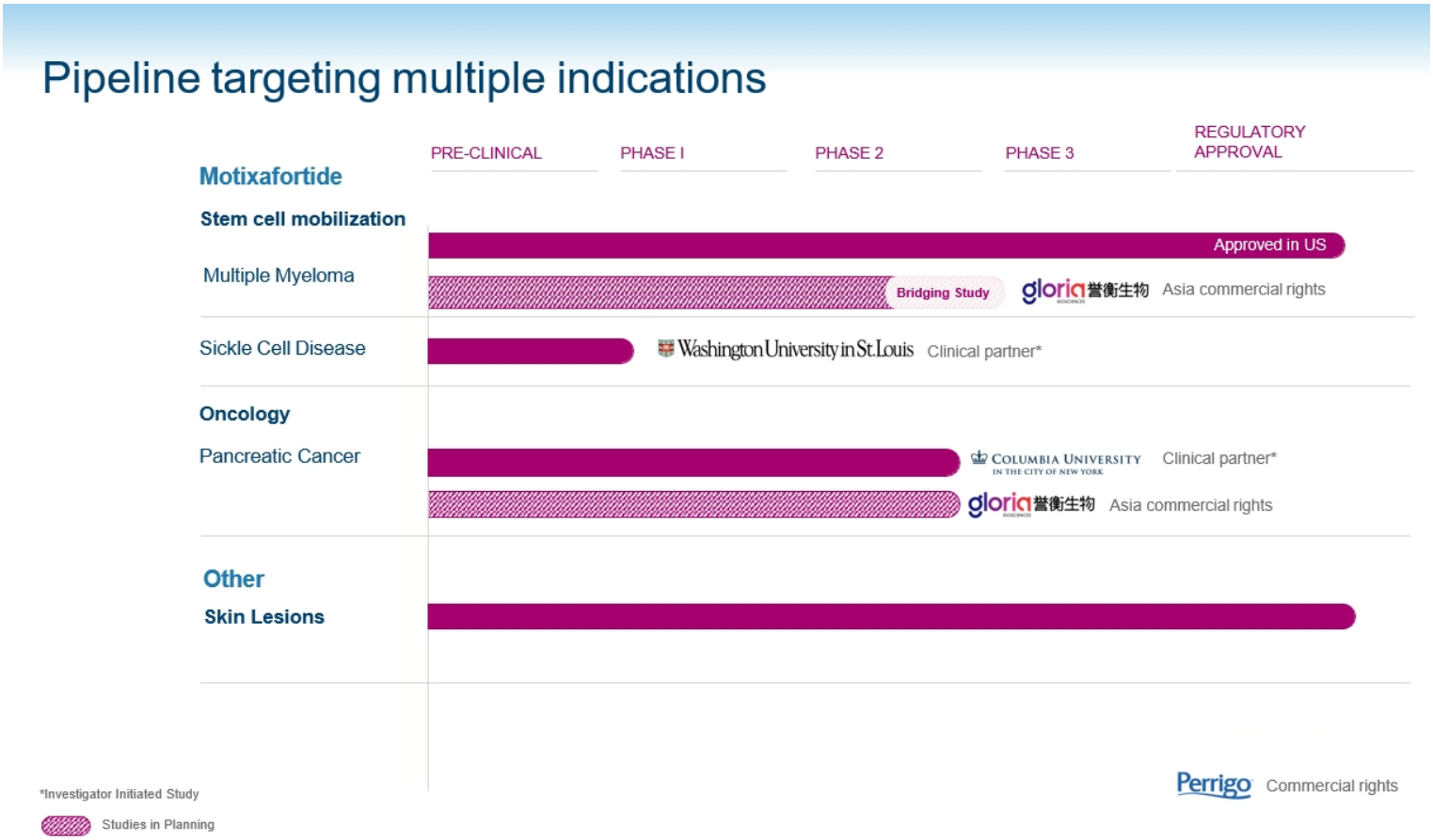
In connection with the License Agreement, on August 27, 2023, we also entered into a securities purchase agreement with HST and Gloria pursuant to which we agreed to sell and issue in a private placement an aggregate of 6,829,137 of our ADSs at a price of $2.136 per ADS. Aggregate gross proceeds from the sale were approximately $14.6 million. The private placement closed in October 2023. No warrants were issued in the transaction.

The License Agreement includes various development obligations for the Licensee pursuant to an agreed-upon development plan, including the execution of a registrational study in stem-cell mobilization and the execution of a randomized Phase 2b study in first-line pancreatic adenocarcinoma.

On August 29, 2023, following the entry into of the License Agreement, we and GenFleet Therapeutics, an immuno-oncology focused biopharmaceutical company based in China, mutually agreed to terminate our collaboration agreement originally entered into in June 2022.

Our Product Pipeline

The table below summarizes key information about our products and our clinical programs:



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 and solid tumors. 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". The FDA-approved trade or brand name of motixafortide is APHEXDA.

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 motixafortide clinical trials.

Stem cell mobilization

Multiple Myeloma

High-dose chemotherapy followed by stem cell transplantation is 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 U.S. and EU. Today, it is estimated that approximately two-thirds, i.e., 65-70% of patients undergoing autologous transplantation in the U.S. receive plerixafor on top of G-CSF. Based on our internal assessment, we estimate the value of the U.S. stem cell mobilization market at approximately $300 million in 2023.

Multiple myeloma is the second most-common hematologic malignancy. Multiple myeloma is an incurable blood cancer that affects certain white blood cells called plasma cells, which are found in the bone marrow. When damaged, these plasma cells rapidly spread and replace normal cells in the bone marrow. According to the American Cancer Society, in 2024, it is estimated that more than 36,000 people will be diagnosed with multiple myeloma, and nearly 13,000 people will die from the disease in the U.S. While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems, or infections.

ASCT is part of the standard treatment paradigm for a number of blood cancers, including multiple myeloma. In the U.S., as many as 8,000 ASCTs are performed each year in patients with multiple myeloma. The success of ASCT depends on adequate mobilization of stem cells during the treatment process. The American Society for Transplantation and Cellular Therapy (ASTCT) guidelines recommend a collection target of 3-5 x 10^6 CD34+ cells/kg and a higher target of double the recommended target if multiple transplants are planned. The International Myeloma Working Group (IMWG) guidelines recommend a collection of 4-6 x 10^6 CD34+ cells/kg with a higher target of 8-10 x 10^6 CD34+ cells/kg to allow for two transplants if needed. Historically, depending on induction regimens and mobilization strategies, up to 47% of patients have had challenges collecting target numbers of hematopoietic stem cells for ASCT after one apheresis session. Increased age, as well as exposure to lenalidomide-containing induction regimens, including 3-4 drug combination regimens, have been associated with impaired stem cell mobilization.

To begin the stem cell mobilization process, a patient will receive a daily dose of G-CSF for four days. Daily doses of G-CSF will continue until the target collection goal is met with the addition of up to four daily doses of plerixafor as needed. For patients unable to mobilize sufficient numbers of cells for harvesting during this primary mobilization phase, rescue therapy may be carried out followed by an additional number of apheresis sessions as necessary.

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 granulocyte colony-stimulating factor, or 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 completed 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 generally well tolerated with a favorable safety profile. In GENESIS, the safety was evaluated in 92 patients with multiple myeloma who received motixafortide 1.25 mg/kg subcutaneously plus G-CSF, and 42 patients who received placebo plus G-CSF. Serious adverse reactions occurred in 5.4% of patients receiving motixafortide plus G-CSF. These reactions included vomiting, injection site reaction, hypersensitivity reaction, injection site cellulitis, hypokalemia and hypoxia. The most common adverse reactions occurring in GENESIS (incidence >20%) were injection site reactions (pain, erythema and pruritus), pruritus, flushing, and back pain. We continue to follow-up on the GENESIS study patients for relapse-free and overall survival, according to the statistical analysis plan agreed upon with the FDA.

In October 2021, we announced positive results from a pharmacoeconomic study evaluating the cost-effectiveness of using motixafortide as a primary stem cell mobilization agent on top of 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) was 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 showed quality-adjusted-life-year (QALY) benefits and net cost savings of approximately $19,000 (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 showed that motixafortide in combination with G-CSF, versus plerixafor in combination with G-CSF, demonstrated 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 showed QALY benefits and net cost savings of approximately $30,000 (not including the cost of motixafortide), versus plerixafor plus G-CSF. The study findings strengthened 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 United States, based on accepted willingness-to-pay (WTP) values for healthcare payers.

In September 2022, we submitted an NDA to the FDA for motixafortide in stem cell mobilization for autologous bone marrow transplantation for multiple myeloma patients and as noted above in September 2023, the FDA approved motixafortide in combination with G-CSF to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma.

In November 2023, we initiated pivotal bridging study preparation activities with Gloria, our Asia partner, to support potential approval and commercialization of motixafortide in stem-cell mobilization in China. In February 2024, an IND was filed with the Center for Drug Evaluation of the National Medical Products Administration in China with regulatory action anticipated in May 2024 and trial commencement in the second half of 2024. See "Item 4.B. Information on the Company — Business Overview—Our Product Pipeline—Out licensing of Motixafortide in Asia".

Sickle Cell Disease

Sickle cell disease, or SCD, is one of the most common genetic diseases globally, affecting millions of people throughout the world and disproportionately impacting persons of color. It is estimated that 5% of the world's population carries trait genes for hemoglobin disorders (including SCD) and in the U.S. it is estimated that 100,000 Americans are affected by SCD Sickle cell disease arises from mutations in the hemoglobin gene, ultimately leading to the production of abnormally shaped (sickle) red blood cells that tend to stick within blood vessels causing their occlusion. The clinical manifestations of SCD include anemia and blood vessel occlusion which can lead to both acute and chronic pain, as well as tissue ischemia across multiple organ systems (e.g., stroke, heart attack, respiratory failure), ultimately compromising end organ function. The cumulative impact of these complications significantly impacts morbidity and mortality for patients with SCD.

Effective HSC-based gene therapies depend upon the collection of significant quantities of stem cells to engineer the treatments that enable the potential genetic treatment of SCD. Currently available mobilization regimens can carry serious risk and side effects for patients with SCD or may not reliably yield optimal numbers of HSCs for gene therapy. Peripheral blood mobilization of stem cells using the mobilization agent plerixafor is the current strategy to collect HSCs for SCD gene therapies.

In March 2023, we entered into a clinical collaboration with Washington University School of Medicine in St. Louis to advance a Phase 1 clinical trial in which motixafortide will be evaluated as a monotherapy and in combination with natalizumab (VLA-4 inhibitor), as novel regimens to mobilize CD34+ hematopoietic stem cells (HSC) for gene therapies in Sickle Cell Disease. The proof-of-concept investigator-initiated study plans to enroll five adults with a diagnosis of SCD who are receiving automated red blood cell exchanges via apheresis. The trial's primary objective is to assess the safety and tolerability of motixafortide alone and in combination with natalizumab in SCD patients, defined by dose-limiting toxicities. Secondary objectives include determining the number of CD34+ hematopoietic stem and progenitor cells (HSPCs) mobilized via leukapheresis; and determining the pharmacokinetics of CD34+ HSPCs mobilization to peripheral blood in response to motixafortide alone and motixafortide plus natalizumab in SCD patients. As anticipated, the study began enrolling in 2023, with first patient dosed in December 2023, and is ongoing (timelines, as well as other study related decisions, are ultimately controlled by the independent investigator-sponsor and are, therefore, subject to change). Initial data from this study is expected in the second half of 2024.

Pancreatic Cancer

Novel, emerging therapeutic approaches for targeting solid tumors in oncology 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. In the United States in 2024, an estimated 66,000 adults will be diagnosed with the disease, which accounts for approximately 3% of all cancers in the U.S. and about 7% of all cancer deaths. Worldwide, an estimated 495,000 people were diagnosed with the disease in 2020. In the U.S., if the cancer is detected at an early stage when surgical removal of the tumor is possible, the 5-year relative survival rate is 44%. About 12% of people are initially diagnosed at this stage. If the cancer has spread to surrounding tissues or organs, the 5-year relative survival rate is 15%. For the 52% of patients who are initially diagnosed with metastatic cancer, the 5-year relative survival rate is 3%. In particular, hepatic (liver) metastases are a critical risk factor driving poor prognoses for patients with metastatic pancreatic adenocarcinoma, or PDAC.

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).

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 mechanism of action and safety of motixafortide in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in 37 patients with metastatic PDAC. The study was an open-label, multicenter, single-arm trial designed to evaluate the mechanism of action, safety and tolerability, and clinical response of the combination of these therapies. The mechanistic evaluation consisted of 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 the recruiting of 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.

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 2b, single-arm study (CheMo4METPANC), led by Columbia University, initially enrolled 11 PDAC patients in a pilot phase. In September 2023, we reported data from the pilot phase of the study. As of July 2023, of those 11 patients, seven patients (64%) experienced a partial response (PR), of which five (45%) were confirmed PRs at the time of the data cut, with one patient experiencing resolution of the hepatic (liver) metastatic lesion. Three patients (27%) experienced stable disease, resulting in a disease control rate of 91%. These findings compare favorably to historic partial response and disease control rates of 23% and 48%, respectively, reported with the chemotherapy combination of gemcitabine and nab-paclitaxel.

Based on this data, the planned single-arm study was amended to a significantly larger, randomized study, based on preliminary pre-defined data from the single-arm pilot phase, with a new planned total of 108 patients. The multi-center CheMo4METPANC Phase 2b clinical trial is a randomized, investigator-initiated clinical trial in first line metastatic pancreatic cancer. Sponsored by Columbia University, and supported equally by BioLineRx and Regeneron, the study is evaluating the combination of motixafortide, PD-1 inhibitor cemiplimab, and standard of care chemotherapies gemcitabine and nab-paclitaxel, versus gemcitabine and nab-paclitaxel, alone in 108 patients. The trial's primary endpoint is progression free survival. Secondary objectives include safety, response rate, disease control rate, duration of clinical benefit and overall survival. In February 2024, the first patient was dosed.

We are also advancing plans in collaboration with Gloria, our Asia partner, for a Phase 2b randomized study assessing motixafortide in combination with the PD-1 inhibitor zimberelimab and standard-of-care chemotherapy as first-line treatment in patients with metastatic pancreatic cancer. IND submission and protocol finalization is expected later in 2024 and study initiation in 2025. See “Item 4.B. Information on the Company — Business Overview—Our Product Pipeline—Out licensing of Motixafortide in Asia”.

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 now expected in 2024 (although timelines are ultimately controlled by the independent investigator and are therefore subject to change).

Other Studies

In addition to the above, from time to time a number of Company-sponsored and investigator-initiated studies may be conducted 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 potentially further elucidate the mechanism of action for motixafortide, generate data about motixafortide’s potential use in other indications, and inform the life-cycle management process of motixafortide. The results of studies such as these are presented from time to time at relevant professional conferences.

Orphan Drug Designations

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). Orphan Drug Designation is granted to therapeutics intended to treat rare diseases or conditions that affect not more than 200,000 people in the United States (or diseases or conditions that affect more than 200,000 people but where there is no reasonable expectation that the product development cost will be recovered from product sales in the United States). If an Orphan Drug-Designated product subsequently receives FDA approval for the disease or condition for which it was designated,, the product is entitled to a seven-year marketing exclusivity period, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances (such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues), for seven years. In addition, Orphan Drug Designation enables sponsors to apply for certain federal grants and tax credits for clinical trials and provides an exemption from the Prescription Drug User Fee so long, as the sponsor’s annual revenue is below $50,000,000.

In January 2020, the EMA granted an Orphan Drug Designation to motixafortide for the treatment of pancreatic cancer. In addition, in December 2023, the EMA granted Orphan Drug Designation to motixafortide for treatment of patients undergoing hematopoietic stem cell transplantation. 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.

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. 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.

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.

Collaboration and Out-Licensing Agreements

Out-Licensing Agreement with Gloria

See "—Out Licensing of Motixafortide in Asia" for details regarding our out-licensing agreement with Gloria.

Out-Licensing Agreement with Perrigo

See "—In-Licensing Agreements— BL-5010" 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 and leverage our U.S. sales and marketing capabilities 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, and achievement of sales milestones.

- 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.

- 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 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 is required to continue until March 2029.

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

The agreement also grants us the right to grant sublicenses for the licensed technology. In the case of a sublicense, we were initially required to pay Biokine a payment of 40% of the amounts we receive as consideration in connection with a sublicense, including royalties, license fees, milestone payments, license maintenance fees and equity, or the Sublicense Receipts. In October 2018, the agreement was amended to reduce the payments associated with sublicensing to 20% of Sublicense Receipts, in return for the payment by us of $10 million in cash plus $5 million in our restricted ADSs. Biokine is also eligible to receive up to a total of $2.5 million in future milestone payments. In the case of self-commercialization, we are obligated to make royalty payments of 10% of net sales, subject to certain limitations.

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 payments 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.

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.

AGI-134

In March 2017, we acquired substantially all of the outstanding shares of Agalimmune and entered into the Agalimmune Development Agreement with the selling shareholders. 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 is designed to not only kill the tumor cells at the site of injection, but also to bring about a durable, follow-on, anti-metastatic immune response. We recently determined to terminate development of AGI-134 and provided notice of our intent to terminate the Agalimmune Development Agreement effective March 15, 2024.

The Agalimmune Development Agreement provides the selling shareholders with a reversionary option, in the event of certain triggering events, including termination by us, that permits the selling shareholders to re-acquire our equity interests in Agalimmune for nominal consideration. We are currently awaiting Agalimmune's founders' decision whether to exercise its reversionary option right.

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, 2024, we owned or exclusively licensed for uses within our field of business 29 patent families that collectively contain 128 granted patents, 4 allowed patent applications and 73 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 composition of matter and methods of manufacturing thereof are covered by patent applications pending in Israel, USA, Europe, Japan, Canada, Australia, China, India, Mexico, Brazil, Hong-Kong and Korea. 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 for the U.S. patents. We also have an exclusive license to a patent family that covers motixafortide combined with a PD1 antagonist for the treatment of cancer. Patents of this family have been granted in the U.S., Israel, Australia, China and Hong Kong; and member patent applications are pending in Australia, Hong Kong, Europe, Japan, China, Canada, India, Korea, Mexico and Brazil. 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 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, China, Australia and New Zealand. The patents will expire in 2033-2034.

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.

Trademarks

We also rely on protection available under trademark laws. As of March 15, 2024, we have registered textual trademarks for "APHEXDA" in Israel, Australia, Brazil, China, EU, UK, Japan and USA, as well as registered logo marks for "APHEXDA" in Israel, Australia, Brazil, China, EU, UK and Japan. We also have the same pending logo trademarks in Canada, Korea and the USA and the same pending textual trademarks in Canada and Korea. We further have pending textual and logo marks for "BioLineRx" in Israel and the USA. We also claim common law protections for other marks we use in our business. Competitors and other companies could adopt similar marks or try to prevent us from using our marks, consequently impeding our ability to build brand identity and possibly leading to customer confusion.

Manufacturing

We rely on contract manufacturers to produce motixafortide for clinical trials and for commercial sale. We have contracted with third-party manufacturers for the manufacture of the API for motixafortide, the supply of finished product for both commercial use and our clinical programs, and for labeling and packaging. In addition, under the License Agreement with HST and Gloria, we expect the Licensee will in the future serve as an additional source for the manufacture of the API for motixafortide. To the extent possible and commercially practicable, we plan to develop back-up strategies for raw materials, manufacturing and testing services for our commercial products. Given the long lead times and cost of establishing additional commercial manufacturing sites, we expect that we will rely on single contract manufacturers to produce motixafortide for the foreseeable future. Our manufacturing partners have a limited number of facilities in which our therapeutic candidates can be produced.

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 therefore are intended to support our projects for research and development activities only. These laboratories are not compliant with current good manufacturing practices, or cGMP. Hence, we cannot independently manufacture drug substances or drug products for our current clinical trials or for commercial distribution.

Our current and any future third-party manufacturers, their facilities and all lots of drug substance and drug products used in our clinical trials and commercial sales are required to be in compliance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements and FDA satisfaction before any product is approved and we can manufacture commercial products. Our current and any future third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreements to resolve allegations of non-compliance with these laws, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and individual imprisonments.

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 life science industry is intensely competitive. We face potential competition from both large and small pharmaceutical and biotechnology companies, academic institutions, governmental and public and private research institutions. 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.

Any therapeutic candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The key competitive factors affecting the success of each therapeutic candidate, if approved, is likely to be their safety, efficacy, convenience, price, the level of proprietary and generic competition, and the availability of coverage and reimbursement from government and other third-party payors. Our competitors may also obtain FDA or other regulatory approval for their therapeutic candidates more rapidly than we may be able to do so for any existing or new product candidates of ours, which could result in their establishing a strong market position before we are able to enter the market.

Motixafortide

Stem cell mobilization

Motixafortide competes directly with Mozobil® (plerixafor), which is marketed by Sanofi Genzyme as a stem cell mobilizer for autologous stem cell transplantation. During the third quarter of 2023, Mozobil's last to expire patent expired. As a result, several companies have launched generic formulations of plerixafor at a substantially reduced price to Mozobil including Dr. Reddy's Laboratories Ltd, Teva Pharmaceuticals USA Inc, Zydus Pharmaceuticals USA Inc, MSN Laboratories Private Ltd, Eugia Pharma Specialities Ltd, Amneal EU Ltd and Kindos Pharmaceuticals Co Ltd.

CXCR4 landscape

We are aware of other CXCR4 inhibitors in various stages of development including burixafor developed by GPCR Therapeutics; X4P-001 (mavorixafor) developed by X4 Pharmaceuticals Inc for WHIM syndrome, AD-214 developed by AdAlta for idiopathic pulmonary fibrosis (IPF), CXCR-4 developed by Alpha 9 Theranostics Inc for unspecified cancer and Balixafortide developed by Spexis AG for the treatment of PDAC and TNBC.

Pancreatic Cancer

Immuno-oncology is an area of great interest in the pharmaceutical market, specifically, immuno-oncology combination therapies. Currently there are thousands 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 competes indirectly with the few, currently approved treatments for PDAC. Motixafortide is believed to modulate the effector/suppressor cell ratio toward a proinflammatory profile, which may act synergistically with checkpoint inhibitor agents to enhance the anti-tumor activity of infiltrated T cells. In the first line setting, Gemcitabine in combination with Abraxane® or FOLFIRINOX regimen are the current standard of care. In February 2024, Ipsen's Onivyde® obtained approval in first line PDAC in the NALIRIFOX regimen based on phase III NAPOLI -3.

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® is approved for maintenance of BRCA mutated pancreatic cancer (approximately 7% of all cases).

In the last several years we have seen a number of late-stage clinical failures of compounds for advanced PDAC, most notably Apexigen's APX005, Erytech's Eryspase and Rafael Pharmaceuticals' devimistat in the last year. Most of these failed trials have been based on a single promising endpoint. Despite a busy early-stage clinical pipeline, there are only a few phase III and approved assets, demonstrating a high attrition rate in PDAC.

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.

Government Regulation

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 of 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 following acceptance of the application for filing. 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 cGMP. 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), or a disease or condition that affects more than 200,000 individuals in the United States but where there is no reasonable expectation that the product development cost will be recovered from product sales 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 regulated under Regulation (EU) 536/2014 (CTR). As opposed to the previous Directive 2001/20/EC (CTD), which as an EU directive was not directly applicable in the member states, the CTR has immediate effect for the whole EU and did not have to be transposed into national law. While national laws implementing the CTD varied to a great extent, the CTR provides for a significant further harmonization of the law governing clinical trials in the EU. After significant delay, the CTR became applicable on January 31, 2022. The CTR now harmonizes the assessment and supervision processes for clinical trials throughout the EU via the Clinical Trials Information System (CTIS), which includes a centralized EU portal and database for clinical trials. From 31 January 2023 onwards, clinical trial sponsors need to apply to start a clinical trial via CTIS. From 31 January 2025, any trials previously approved under the CTD that continue to run after such date, will need to comply with CTR and their sponsors must have recorded the required information on such trials in CTIS. 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 1-3) 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 EC2017/1572 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use for human use and Volume 4 of the "Rules Governing Medicinal Products in the European Community". Directive 2017/1572/EU has replaced Directive 2003/94/EC. Directive 2003/94/EC will still be applicable to clinical trials conducted in accordance with the former regime under transitional provisions. 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 the CTR and Directive 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 the CTR or if conducted prior to 31 January 2022, its predecessor Directive 2001/20/EC. The conduct of a clinical trial in the EU requires, pursuant to the CTR, 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.

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.

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.

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 the head of the medical center in which the clinical studies are planned 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 the head of the medical center. Israeli Ministry of Health, except for certain circumstances, is required to approve each trial as well. 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 head of medical center 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 and our collaborators are subject to numerous and a variety of regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy governing, among other things, clinical trials, marketing authorization, manufacturing, 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 or our collaborators can commence clinical trials, manufacturing or marketing of the product in those countries. The approval process varies from country to country and may involve additional product testing and additional administrative review periods. As a result, 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. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

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.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic, health outcome studies in order to demonstrate the medical necessity, quality of life benefits, and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective in light of cost-benefit analysis. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, ensuring adequate coverage and payment for our therapeutic candidates will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct studies that compare the cost effectiveness of our product candidates or products to other available therapies. The conduct of such studies could be expensive and result in delays in our commercialization efforts.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies in order to obtain reimbursement. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control company profits and issue guidance to prescribers. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, reference pricing and cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Other Healthcare Laws and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, a scheme or making false statements in connection with the delivery of or payment for health care benefits, items, or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on covered entities and their business associates that associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf;

- the Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or collectively the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, within HHS, information related to payments and other transfers of value to certain healthcare providers and teaching hospitals and information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

U.S. Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established the Center for Medicare & Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

We expect that future changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

Additionally, on December 20, 2019, the Further Consolidated Appropriations Act for 2020 was signed into law (P.L. 116-94) and includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019, or the CREATES Act. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples of an RLD to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on any of our future commercial products are unknown.

More recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. The IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in recent years, several states have formed prescription drug affordability boards (PDABs). Much like the IRA's drug price negotiation program, these PDABs have attempted to implement upper payment limits (UPLs) on drugs sold in their respective states in both public and commercial health plans. In August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The Federal Trade Commission (FTC) in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including pharmaceutical product developers like us.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Israeli Government Programs

Israel Innovation Authority

A number of our therapeutic products have been financed, in part, through funding from the IIA in accordance with Research Law. Through December 31, 2023, 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, 2023, we had 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 in connection with our in-licensing of motixafortide (which liability has no relation to the funding actually received by us) amounted to $3.2 million as of December 31, 2023. We have a full right of offset for amounts payable to the IIA for motixafortide 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 (and associated services) developed with the support of the IIA are payable to the Israeli government, generally at the rate of 3% (and at an increased rate under certain circumstances, as described below). 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. Until October 25, 2023, the interest was calculated at a rate based on the last published 12-month LIBOR applicable to U.S. dollar deposits. On October 25, 2023, the IIA published a directive concerning changes in royalties to address the expiration of the LIBOR, according to which, (a) for IIA grants approved between January 1, 1999 and June 30, 2017 – the annual interest will be the interest in effect at the time of the grant approval; (b) for IIA grants approved between July 1, 2017 and December 31, 2023 – for the period prior to December 31, 2023, the interest shall be calculated based on the 12-month LIBOR applicable to U.S. dollar deposits, as published on the first trading day of each year or in an alternative publication of the Bank of Israel; and for periods as of January 1, 2024, the annual interest shall be calculated at a rate based on the 12-month secured overnight financing rate (SOFR), or at an alternative rate published by the Bank of Israel plus 0.71513%; and (c) for IIA grants approved on or following January 1, 2024, the annual interest shall be the higher of (i) the 12 months SOFR interest rate, plus 1%, and (ii) a fixed annual interest rate of 4%.

Pursuant to the Research Law and the tracks published by the IIA, recipients of funding from the IIA are restricted from manufacturing outside of Israel products developed using IIA grants or derived from technology developed with IIA grants (except to the extent that the IIA approved grant program includes a pre-determined portion of manufacturing that may be performed outside Israel) and from transferring rights to manufacture such products outside of Israel, without the prior IIA approval (except for the transfer of up to 10% of the manufacturing capacity in the aggregate, which requires only a notice to the IIA). The IIA may, in special cases, approve the transfer outside of Israel of manufacture or of manufacturing rights of a product developed in an approved program or which resulted therefrom (in excess of any pre-determined percentage included in the IIA grant approval, if any). If we were to receive such IIA 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 (up to 150% of the grant amounts plus interest), depending on the portion of total manufacturing to be performed outside of Israel. In addition, the royalty repayment rate applicable to us could possibly increase in such event.

In addition, 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, which we may not receive. Generally, such IIA approval would be subject to making a payment to the IIA of a redemption fee, calculated in accordance with the applicable formula set out in the tracks published by the IIA, which may be in the amount of up to six times the amount of the grants received (less paid royalties, if any, and depreciation, but no less than the total grants received), plus accrued interest. 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.

Approval of the transfer or license of technology to residents of Israel is also 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. Additionally, a royalty payment is generally required to be made from the consideration paid for such transfer.

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.

Even following the full repayment of any IIA grants, we must nevertheless continue to comply with the requirements of the Research Law. If we fail to comply with any of the conditions and restrictions imposed by the Research Law and regulations and guidelines thereunder, or by the specific terms under which we received the grants, we may be required to refund any IIA grants previously received together with interest and penalties, and, in certain circumstances, may be subject to criminal charges.

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."

C. Organizational Structure

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

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 123,800 (approximately $33,000), 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.

In addition, in October, 2022, we entered into a lease agreement for our office in Waltham, Massachusetts for an aggregate of 4,880 square feet of space. Monthly rent is $23,600. The term of the lease expires in December 2024.

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." Our discussion and analysis for the year ended December 31, 2021 can be found in Item 5. "Operating and Financial Review and Prospects" of our Annual Report on Form 20-F for the fiscal year ended December 31, 2022, filed with the SEC on March 22, 2023 (File No. 001-35223).

We are a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases. Our primary commercialization pipeline consists of APHEXDA (motixafortide), a novel peptide for the treatment of stem-cell mobilization and solid tumors, which on September 8, 2023, was approved by the FDA, for use in combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma. We are also advancing the development of motixafortide for patients with sickle cell disease, pancreatic cancer and other solid tumors. In addition, we have an off-strategy, legacy therapeutic product called BL-5010 for the treatment of skin lesions.

We seek to develop and commercialize 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. 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. Our strategy includes commercializing our therapeutic candidates by way of out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case-by-case basis, the commercialization of our therapeutic candidates independently. In this regard, we are currently executing on an independent commercialization plan for APHEXDA in stem cell mobilization for autologous bone marrow transplantation in multiple myeloma patients.

With headquarters and development operations in Israel, and commercialization operations in the U.S., we are driving innovative therapeutics with end-to-end expertise in development and commercialization, ensuring life-changing discoveries move beyond the bench to the bedside.

A. Operating Results

History of Losses

Since our inception in 2003, we have generated significant losses in connection with our research and development, and more recently, our commercialization activities. As of December 31, 2023, we had an accumulated deficit of $391 million. We expect to continue to generate losses in connection with our research and development activities relating to our pipeline of therapeutic candidates and commercialization of APHEXDA until we reach commercial profitability, if ever. Such research and development and commercialization 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 and we expect to need to obtain additional funds to further pursue our research and development programs and commercialization plans.

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), payments received under our strategic licensing and collaboration arrangements, funding received from the IIA, and interest earned on investments. We expect to continue to fund our operations over the next several years through our existing cash resources, the commercialization of APHEXDA, 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 any other out-licensing transaction, interest earned on our investments, and additional capital to be raised through public or private equity offerings or debt financings. As of December 31, 2023, we held $43.0 million of cash, cash equivalents and short-term bank deposits.

Revenues

Our revenues to date have been generated primarily from milestone payments under out-licensing agreements and more recently, revenues from product sales of APHEXDA.

We expect our revenues, if any, for the next several years to be derived primarily from the independent commercialization of APHEXDA in stem cell mobilization in the U.S. and milestone payments from the license agreement with HST and Gloria, including future royalties on product sales from such out-licensing agreements.

Cost of Revenues

Our cost of revenues to date have consisted of sub-license payments to the licensors in respect of upfront and milestone payments associated with out-licensing agreements and more recently, costs associated with the manufacture of APHEXDA. Prior to receiving FDA approval for APHEXDA in September 2023, we expensed such manufacturing and material costs as research and development expenses.

We expect our cost of revenues, if any, for the next several years to be derived primarily from the costs associated with the manufacture of APHEXDA, royalties payable to the licensors stemming from direct product sales related to the independent commercialization as set forth above, as well as from sub-license payments to the licensors in respect of out-licensing agreements and other potential collaboration arrangements, including future royalties on product sales from such out-licensing agreements.

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 therapeutic 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 expenses to remain one of our primary expenses in the near future as we continue to develop motixafortide.

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

Project	Status		Expected Near Term Milestones	
motixafortide	1.	FDA approval received on September 8, 2023 for stem-cell mobilization in multiple myeloma patients.	1.	Commercialization ongoing
	2.	Reported data from single-arm pilot phase of the investigator-initiated Phase 2 combination trial in first-line PDAC. Of 11 patients with metastatic pancreatic cancer enrolled, 7 patients (64%) experienced partial response (PR), of which 5 (45%) were confirmed PRs with one patient experiencing resolution of the hepatic (liver) metastatic lesion. 3 patients (27%) experienced stable disease, resulting in a disease control rate of 91%. Based on these encouraging results, study was substantially revised to a multi-institution, randomized trial of 108 patients	2.	First patient dosed in February 2024 and currently enrolling*
	3.	Phase 1b study in patients with ARDS secondary to COVID-19 and other respiratory viral infections	3.	Data from the study is anticipated in 2024*
	4.	Phase 1 study for gene therapies in SCD	4.	First patient does in December 2023 and data from the study is expected in the second half of 2024*
	5.	Pivotal bridging study in SCM in China under license agreement with Gloria	5.	Initiation of the study is expected in second half of 2024
	6.	Phase 2b randomized study in first-line PDAC in China under license agreement with Gloria	6.	IND submission and protocol finalization expected in 2024 and study initiation in 2025

*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 expenses 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 motixafortide in our pipeline for commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test motixafortide and any other therapeutic candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each such 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 the U.S. commercialization of motixafortide, and a life-cycle expansion and management program for other therapeutic indications for motixafortide, our future research and development expenses will depend on the clinical success of motixafortide in these other indications, and 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.

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, and are eligible to participate, in the clinical trials;
- the duration of patient follow-up;
- whether the patients require hospitalization or can be treated on an outpatient basis;

- the development stage of the therapeutic candidate; and
- the efficacy and safety profile of the therapeutic candidate.

The lengthy process of completing clinical trials and seeking regulatory approval for our therapeutic 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 commercialization, marketing and business development functions. Other significant costs include marketing and communication materials, market access activities, professional fees for outside market research and consulting, and legal services related to compliance and to potential business development transactions.

We expect our sales and marketing expenses to become our most significant cost as we advance our U.S. commercialization plan for motixafortide in stem cell mobilization for autologous bone marrow transplantation for multiple myeloma patients.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including accounting, finance, legal, compliance, 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 February 2019, May-June 2020 and September 2022. 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 an "at-the-market" offering agreement, or ATM Agreement, between us and H.C. Wainwright & Co., LLC, or HCW, entered into in September 2021, and the pro-rata share of issuance expenses from the placements related to the warrants. Sales-based royalties 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 loans 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.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in conformity with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. In preparing our consolidated financial statements, we make judgements, estimates and assumptions about the application of our accounting policies which affect the reported amounts of assets, liabilities, revenue and expenses. Our critical accounting judgements and sources of estimation uncertainty are described in Note 4 to our consolidated financial statements, which are included elsewhere in this Annual Report.

Revenue Recognition

We account for contract revenues in accordance with International Financial Reporting Standards No. 15, or IFRS 15. 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.

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 commercialization, clinical trials, and preclinical development. 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.

Share-based Compensation

We account for share-based compensation arrangements in accordance with the provisions of IFRS 2. IFRS 2 requires companies to recognize share 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 share-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 shares, risk-free interest rates, estimated life of the equity instruments issued and the market price of our shares. 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 a loan transaction entered into with Kreos Capital in October 2018, 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 were 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. The warrants expired in February 2024.

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 were 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. The warrants expired in November 2022.

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 were 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. The warrants expired in November 2022.

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.

In connection with a registered direct offering we completed in September 2022, we issued warrants to purchase 13,636,365 ADSs at an exercise price of $1.15 per ADS, of which warrants to purchase 2,545,455 have been exercised. The warrants were exercisable for a period of five years from the date of issuance. Since the exercise price of those warrants were 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. We also issued warrants to purchase 681,818 ADSs at an exercise price of $1.375 per ADS. The warrants are exercisable for a period of five years from the date of issuance and have been classified as shareholder's equity.

Results of Operations – Overview

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

Revenues

Revenues for the year ended December 31, 2023 were $4.8 million. We did not record any revenues for the year ended December 31, 2022. The revenues in 2023 (all of which were recorded in the fourth quarter of 2023) primarily reflect a portion of the up-front payment received by us for the License Agreement, of which $4.6 million was recognized in 2023, as well as $0.2 million of revenues from product sales of APHEXDA in the U.S.

Cost of revenues

Cost of revenues for the year ended December 31, 2023 was $3.7 million. We did not record any cost of revenues for the year ended December 31, 2022. The cost of revenues in 2023 primarily reflects Biokine's share of the up-front payment received by us for the License Agreement and of the net sales.

Research and development expenses

Research and development expenses for the year ended December 31, 2023 were $12.5 million a decrease of $5.1 million, or 29.0% compared to $17.6 million for the year ended December 31, 2022. The decrease resulted primarily from lower expenses related to NDA supporting activities related to motixafortide, as well as lower expenses associated with the completion of the AGI-134 study.

Sales and marketing expenses

Sales and marketing expenses for the year ended December 31, 2023 were $25.3 million, an increase of $18.8 million, or 291.1% compared to $6.5 million for the year ended December 31, 2022. The increase resulted primarily from the ramp-up of pre-commercialization and commercialization activities related to motixafortide.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2023 were $6.3 million, an increase of $1.2 million, or 24.6% compared to $5.1 million for the year ended December 31, 2022. The increase resulted primarily from an increase in payroll and related expenses associated with a small head-count increase during the 2022 period, as well as an increase in professional services and legal expenses.

Impairment of intangible assets

Impairment of intangible assets expenses for the year ended December 31, 2023 were $6.7 million. We did not record any impairment of intangible assets for the year ended December 31, 2022. This non-cash expense in 2023 reflects the impairment of the intellectual property related to AGI-134 resulting from our decision to terminate its development.

Non-operating income (expense), net

We recognized net non-operating expenses of $10.8 million for the year ended December 31, 2023 compared to net non-operating income of $5.7 million for the year ended December 31, 2022. Non-operating expenses for the year ended December 31, 2023 primarily relates to non-cash, fair-value adjustments of warrant liabilities on our balance sheet. Non-operating income for the year ended December 31, 2022 primarily relates to non-cash, 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 $0.1 million for the year ended December 31, 2023 compared to net financial expenses of $1.5 million for the year ended December 31, 2022. Net financial expenses for both periods primarily relate to interest paid on loans, offset by investment income earned on our bank deposits.

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. As of December 31, 2023, we held $43.0 million of cash, cash equivalents and short-term bank deposits. We have invested substantially all our available cash funds in short-term bank deposits.

In August 2023, we entered into the License Agreement with HST and Gloria, pursuant to which we granted HST an exclusive, royalty-bearing, sublicensable license with respect to the intellectual property rights and know-how associated with motixafortide in order to develop and commercialize motixafortide in in Asia (other than Israel and certain other countries) and to engage and authorize Gloria to perform services under the License Agreement in such territory. Pursuant to the terms of the License Agreement, the Licensee made a $15 million upfront payment in October 2023, upon the closing of the transaction. In connection with the License Agreement, in August 2023, we also entered into a securities purchase agreement with HST and Gloria pursuant to which we agreed to sell and issue in a private placement an aggregate of 6,829,137 of our ADSs. Aggregate gross proceeds from the sale were approximately $14.6 million. The private placement closed in October 2023.

In September 2022, we entered into a loan agreement, or the Loan Agreement, with Kreos Capital VII Aggregator SCS, or Kreos Capital. Under the Loan Agreement, Kreos Capital will provide the Company with access to term loans in an aggregate principal amount of up to $40 million in three tranches as follows: (a) a loan in the aggregate principal amount of up to $10 million, available for drawdown upon closing of the Loan Agreement and until April 1, 2023, (b) a loan in the aggregate principal amount of up to $20 million, available for drawdown upon achievement of certain milestones and until April 1, 2024, and (c) a loan in the aggregate principal amount of up to $10 million, available for drawdown upon achievement of certain milestones and until October 1, 2024. We drew down the initial tranche of $10 million following execution of the agreement in September 2022.

In September 2022, we entered into definitive agreements with certain institutional investors providing for the issuance and sale in a registered direct offering of 13,636,365 of our ADSs and warrants to purchase up to an aggregate of 13,636,365 ADSs at a combined purchase price of $1.10 per ADS and associated investor warrant, for aggregate gross proceeds of $15 million. The transaction closed in September 2022.

In September 2021, we entered into the ATM 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 the issuance date of this report, we have sold 2,109,858 of our ADSs for total gross proceeds of approximately $4.4 million under the ATM program.

Net cash used in operating activities was $22.6 million for the year ended December 31, 2023, compared with net cash used in operating activities of $26.2 million for the year ended December 31, 2022. The $3.6 million decrease in net cash used in operating activities in 2023 was primarily the result of increases in contract liabilities as well as accounts payable and accruals, partially offset by an increase in sales and marketing expenses.

Net cash provided by investing activities was $1.4 million for the year ended December 31, 2023, compared to net cash provided by investing activities of $4.0 million for the year ended December 31, 2022. The changes in cash flows from investing activities relate primarily to investments in, and maturities of short-term bank deposits.

Net cash provided by financing activities was $15.1 million for the year ended December 31, 2023, compared to net cash provided by financing activities of $20.4 million for the year ended December 31, 2022. The cash flows in 2023 primarily reflect the private placement of ADSs to HST and Gloria, warrant exercises and net proceeds from the ATM facility, offset by repayments of the loan from Kreos Capital and the repayments of lease liabilities. The cash flows in 2022 primarily reflect the underwritten public offering of our ADSs in September 2022 and the net proceeds of a loan from Kreos Capital, offset by repayment of a previous loan from Kreos Capital.

We have incurred accumulated losses in the amount of $391 million through December 31, 2023, and we expect to continue incurring losses and negative cash flows from operations until our product or products reach commercial profitability. Management monitors rolling forecasts of our liquidity reserves on the basis of anticipated cash flows and maintains liquidity balances at levels that are sufficient to meet its needs. The execution of an independent commercialization plan for motixafortide in the United States implies an increased level of expenses prior to and following launch of the product. Therefore, our cash flow projections are subject to various risks and uncertainties concerning their fulfilment, and these factors and the risk inherent in our operations, which management has concluded indicate that a material uncertainty exists, may cast significant doubt on our ability to continue as a going concern. Similarly, our independent registered public accounting firm included a “going concern” explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2023.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Based on our current projected cash requirements, we believe that our existing cash and investment balances and other sources of liquidity, including net product revenues from product sales of APHEXDA and milestone payments from the License Agreement, will be sufficient to meet our capital requirements into 2025. We expect to also continue to seek to finance our operations through other sources, including commercialization in the United States for APHEXDA, 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. 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, if any, under our collaboration or licensing arrangements;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval of our therapeutic candidates;
- our success in effecting out-licensing arrangements with third parties;

- the ability of our collaborators and licensees to achieve development milestones, marketing approval and other events or developments under our collaboration and out-licensing 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 therapeutic candidates;
- the magnitude of our general and administrative expenses;
- interest and principal payments on the loan from Kreos Capital;
- 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 any resurgence of the COVID-19 pandemic, the Russian invasion of Ukraine, and the military campaigns by Israel against Hamas and other terrorist organizations (including the declaration of war by Israel against Hamas), which may exacerbate the magnitude of the factors discussed above.

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, 2023:

	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
			(in thousands of U.S. dollars)		
Car leasing obligations	300	161	139	-	-
Premises leasing obligations	2,231	575	584	613	459
Purchase commitments	6,911	6,578	308	25	-
Total	9,442	7,314	1,031	638	459

The premises leasing obligations in the foregoing table include our commitments under the lease agreement for our facility in Modi'in, Israel and our facility in Waltham, Massachusetts. See "Item 4. Information on the Company — Property, Plant and Equipment." As for our facility in Israel, 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 $25,000. In addition, we pay building maintenance charges of $8,000 per month. As for our facility in the United States we entered into a lease agreement in October 2022. The monthly lease fee is $23,600. The term of the lease expires in December 2024.

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

D. Trend Information

We are a commercial stage biopharmaceutical 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

Our consolidated financial statements are prepared in conformity with IFRS, as issued by the IASB. In preparing our consolidated financial statements, we make judgements, estimates and assumptions about the application of our accounting policies which affect the reported amounts of assets, liabilities, revenue and expenses. Our critical accounting judgements and sources of estimation uncertainty are described in Note 4 to our consolidated financial statements, which are included elsewhere in this Annual Report.

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 25, 2024. 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	64	Chief Executive Officer
Mali Zeevi, CPA	48	Chief Financial Officer
Ella Sorani, Ph.D.	56	Chief Development Officer
Holly W. May, MBA	62	U.S. President
Aharon Schwartz, Ph.D. (1)	81	Chairman of the Board of Directors, Class III Director
Rami Dar, MBA (1)(2)(3)(4)	67	Class I Director
B.J. Bormann, Ph.D. (1)(3)	65	Class II Director
Raphael Hofstein, Ph.D. (1)(2)(3)	74	Class II Director
Avraham Molcho, M.D. (1)(2)(3)	66	Class I Director
Sandra Panem, Ph.D. (1)	77	Class III Director
Shaoyu Yan, Ph.D.	59	Class III Director
Gal Cohen (1)	51	Class I Director

(1) Independent director under applicable Nasdaq Capital Market, as affirmatively determined by our board of directors.

(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, Mr. Serlin served as the Chief Financial Officer of Tescom Software Systems Testing Ltd., an IT services company publicly traded in both Tel Aviv and London. Mr. Serlin's 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 certified public accountant and holds a B.Sc. degree 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 certified public accountant at Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited. Ms. Zeevi is a certified public accountant and holds a B.A. degree 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. degree in chemistry and an M.Sc. degree and Ph.D. in pharmacology, all from Tel Aviv University.

Holly W. May, MBA, has served as our U.S. president since September 2022. From June 2022 to August 2022, Ms. May served as our Chief Commercial Officer. Prior to joining BioLineRx, Ms. May served as Chief Commercial Officer at AVROBIO from September 2019, where she was responsible for building the company's global commercial organization and over-arching commercial capabilities, inclusive of driving the development and execution of commercial strategy. Prior to that, Ms. May served as Vice President and Head of Commercial at SOBI, Inc., where she led all aspects of commercial strategy, operations and performance. Prior to joining SOBI, Ms. May held leadership roles of increasing strategic importance across marketing, operations, sales, and planning at Sanofi and Genzyme, with her last roles encompassing Vice President in the Genzyme rare disease unit, and Head of Marketing, Operations and Strategic Planning for Sanofi's global oncology division. Ms. May holds a BA degree in Zoology from Miami University of Ohio, and an MBA degree with a concentration in marketing from the University of Akron.

Aharon Schwartz, Ph.D., has served as the Chairman of our board of directors since 2004. Dr. Schwartz served in a number of positions at 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). Dr. Schwartz also works as an independent consultant. Dr. Schwartz received his Ph.D. in organic chemistry from the Weizmann Institute of Science, an M.Sc. degree in organic chemistry from the Technion – Institute of Technology and a B.Sc. degree 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.

Rami Dar, MBA, has served on our board of directors (as an external director, within the meaning of the Companies Law, until March 25, 2024) since July 2022 and as a member of our Audit Committee and Compensation Committee since such time and has served as a member of our Investment Monitoring Committee since July 2022. Mr. Dar has served as a board member of BetterSeeds Ltd since November 2023 and served as a board member of Nordia Springs since March 2020. From 2018 to 2023, Mr. Dar served as chairman of Novolog Ltd. (TLV: NVLG). From 2002 to 2019, Mr. Dar served as Chief Executive Officer of Hazera Seeds Ltd. (formerly Hazera Genetics), a leading global seed company, and prior to that, from 1998 to 2002, served in various management positions at Teva Pharmaceuticals Ltd., including as Business Development Executive from 2001 to 2002, Chief Executive Officer of Teva Medical Ltd., from 1998 to 2001, and Chief Executive Officer of Teva Pharmaceuticals Ltd. Israel from 1995 to 1998. Mr. Dar holds a B.A. degree in economics and philosophy and an M.A. degree in economics, both from the Hebrew University of Jerusalem, Israel, and an Executive M.B.A. from Columbia University, New York, USA.

BJ Bormann, Ph.D., has served on our board of directors since August 2013 and on our Compensation Committee since 2022. Dr. Bormann previously served 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, Dr. Bormann 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. degree 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. Dr. Hofstein 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. degree from the Weizmann Institute of Science, and his B.Sc. degree in chemistry and physics from the Hebrew University of 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 on our board of directors since 2010 (as an external director, within the meaning of the Companies Law, until March 25, 2024) 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, Dr. Molcho became the co-founder of Ayana Pharma Ltd. (formerly DoxoCure), a privately-held company engaged in the manufacturing of liposome-based therapeutics. Dr. Molcho 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. Dr. Molcho 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 degree from Tel-Aviv University Recanati Business School.

Sandra Panem, Ph.D., has served on our board of directors since February 2014. Dr. Panem served as a managing partner at Cross Atlantic Partners, from 2000 2023. Dr. Panem 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, Dr. Panem 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. Dr. Panem received a B.S. degree in biochemistry and a Ph.D. in microbiology from the University of Chicago.

Shaoyu Yan, Ph.D., has served on our board of directors since November 2023. Dr. Yan has over 30 years' experience in drug research and development, manufacturing, and management, including more than 15 years working with pharmaceutical companies, contract research organizations and marketing authorization holders under regulation of National Medical Products Administration of China (NMPA). Since March 2020, Dr. Yan has served as an executive vice president and head of R&D and manufacturing at Gloria Biosciences Co. Ltd. From February 2014 to December 2019, Dr. Yan served as the senior director and senior research fellow of the oncology and immunology business unit at WuXi AppTec (Shanghai) Co., Ltd. (SHA: 603259). Prior to these roles, Dr. Yan held positions, including at various academic institutions, including: senior research scientist at the department of thoracic and cardio surgery and pharmaceutical development center of the University of Texas's MD Anderson Cancer Center from June 2006 to December 2013; visiting scholar and research scientist of the faculty of pharmaceutical sciences at Kyushu University from August 2001 to August 2002; deputy director in the institute of medical raw materials at Tianjin Pharmaceutical Group Corp. and director and co-founder at the Shenyang Huiming Institute of Chinese Traditional Medicine from May 1995 to August 1998. Dr. Yan received a Ph.D in pharmaceutical science and M.Sc. degree in pharmaceutics from Shenyang Pharmaceutical University, and a B.Sc. degree from Jilin University in polymer chemistry. Dr. Yan completed his postdoctoral training in the field of pharmacology and biochemistry from Michael E. DeBakey Department of Surgery at Baylor College of Medicine from February 2003 to June 2006. Dr. Yan was appointed to serve as a Class III director by our board of directors pursuant to the securities purchase agreement that we entered into with HST and Gloria in August 2023 See "Item 7B. Major Shareholders and Related Party Transactions - Related Party Transactions - Gloria License Agreement and Securities Purchase Agreement."

Gal Cohen, MBA, has served on our board of directors since December 2023. Mr. Cohen has served since April 2020 as Chairman of the board of directors and Chief Executive Officer of Quark Pharmaceuticals, Inc., and also serves on the boards of directors of Ayana Pharma Ltd. and Silver Castle Holdings Ltd (TASE: SLCL). From November 2006 to May 2019, Mr. Cohen served as President and Chief Executive Officer of MediWound Ltd., leading the development of their innovative biological drug for burn treatment up to marketing authorization and commercialization in numerous international markets, as well as their initial public offering on Nasdaq. Prior to that, from 2004 to 2006, Mr. Cohen served as Director of Strategic Business Planning and New Ventures at Teva Pharmaceuticals Ltd. From 2000 to 2004, Mr. Cohen served at Teva's Global Products Division as Project Manager for the launch of Copaxone® in Europe and numerous other countries, and from 1998 to 2000, he led projects at Teva's Corporate Industrial Engineering Department. Mr. Cohen holds a B.Sc. degree in Industrial Engineering and Management (*cum laude*) from the Technion-Israel Institute of Technology and an M.B.A. degree (*cum laude*) from Tel Aviv University.

On March 25, 2024, Dr. Michael Anghel, who served on our board of directors and on our Investment Monitoring Committee (as Chairperson) from 2010, notified us of his resignation from the board of directors effective immediately for personal reasons.

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 2022. 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 exculpating them, to the fullest extent permitted by law, from liability to us for damages caused to us as a result of a breach of duty of care, and undertaking 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' liability insurance. The terms of these agreements and of our directors' and officers' liability insurance are consistent with the provisions of the Compensation Policy. See "Item 6.C — Directors, Senior Management and Employees — Board Practices — Exculpation, insurance and indemnification of office holders."

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, 2023. 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 14 persons	2,483	1,259

The following table presents information regarding compensation actually received or accrued by our five most highly compensated executive officers during the year ended December 31, 2023.

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	280	81	215	354	22	952
Mali Zeevi Chief Financial Officer	182	53	119	69	20	443
Ella Sorani Chief Development Officer	206	70	156	68	20	520
Holly W. May President BioLineRx USA, Inc.	420	130	160	304	-	1,014
Tami Rachmilewitz Chief Medical Officer *	157	54	-	-	15	226

*Until October 31, 2023

(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, 2023.

(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."

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

C. Board Practices

Board of Directors

According to the Companies Law, the management of our business is vested in our board of 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.

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 under Israeli law (if any). Currently, our board of directors consists of nine directors. Our board of directors has determined that each of our directors other than Mr. Yan is an "independent director" under Nasdaq Listing Rules.

Under our Articles of Association, as amended at our annual general meeting of shareholders held in August 2023, our directors (other than external directors, if any) are divided into three classes with staggered three-year terms. Each class of directors consists, as nearly as possible, of one-third of the total number of directors constituting the entire board of directors. At each annual general meeting of our shareholders beginning in 2024, the election or re-election of directors following the expiration of the term of office of the directors of that class of directors will be for a term of office that expires on the third annual general meeting following such election or re-election. Each director (other than external directors, if any) holds office until the third annual general meeting of our shareholders and until his or her successor is duly appointed, unless the tenure of such director expires earlier pursuant to the Companies Law, or unless removed from office as described below.

Our directors are divided among three classes as follows:

- the Class I directors, consisting of Dr. Avraham Molcho, Mr. Rami Dar and Gal Cohen, will hold office until our annual general meeting of shareholders to be held in 2024;
- the Class II directors, consisting of Dr. B.J. Bormann and Dr. Raphael Hofstein, will hold office until our annual general meeting of shareholders to be held in 2025; and
- the Class III directors, consisting of Dr. Sandra Panem, Dr. Aharon Schwartz and Dr. Shaoyu Yan, will hold office until our annual general meeting of shareholders to be held in 2026.

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 our board of directors may appoint directors (other than external directors) to fill vacancies on our board of directors, including if the number of directors is below the maximum number of directors who may serve as provided in our Articles of Association, for a term of office equal to the remaining period of the term of office of the director(s) whose office(s) has been vacated, or in case of a vacancy due to the number of directors serving being less than the maximum number stated in our Articles of Association, until the next annual general meeting of our shareholders for the class he or she has been assigned by our board of directors.

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. Our board of directors has determined that Rami Dar has such financial and accounting expertise.

Chairperson of the Board. Under the Companies Law, a person cannot hold the role of both chairperson 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 chairperson of the board of directors of that company and the chairperson 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 chairperson of the board of directors of such a subsidiary.

DIVERSITY OF THE BOARD OF DIRECTORS
Board Diversity Matrix (As of March 25, 2024)

Country of Principal Executive Offices	Israel
Foreign Private Issuer	Yes
Disclosure Prohibited under Home Country Law	No
Total Number of directors	8

Part I: Gender Identity	**Female**	**Male**	**Non-Binary**	**Did Not Disclose Gender**
directors	2	6	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction		0		
LGBTQ+		0		
Did Not Disclose Demographic Background		0		

External directors

Under the Companies Law, the boards of directors of companies whose shares are publicly traded, including companies with shares listed on the Nasdaq Capital Market, are required to include at least two members who qualify as external directors. Pursuant to the Israeli Companies Regulations (Relief for Companies the Shares of which are Registered for Trading Outside of Israel) – 2000, or the Relief Regulations, companies that do not have a controlling shareholder (within the meaning of the Companies Law) with shares traded on certain U.S. stock exchanges, including the Nasdaq Capital Market, may, subject to certain conditions, "opt out" from the Companies Law requirements to appoint external directors and related Companies Law rules concerning the composition of the audit committee and compensation committee of the board of directors (other than the gender diversification rule under the Companies Law, which requires the appointment of a director from the other gender if at the time of appointment of a director all members of the board of directors are of the same gender).

On March 25, 2024, in accordance with the Relief Regulations, our board of directors elected to "opt out" from the Companies Law requirement to appoint external directors and related Companies Law rules concerning the composition of the audit committee and compensation committee of the board of directors, effective immediately. Under the Relief Regulations, the exemption from such Companies Law requirements will continue to be available to us so long as: (i) we do not have a "controlling shareholder" (as such term is defined under the Companies Law), (ii) our shares are traded on certain U.S. stock exchanges, including the Nasdaq Capital Market, and (iii) we comply with the director independence requirements and the audit committee and compensation committee composition requirements under U.S. laws (including applicable Nasdaq Rules) applicable to U.S. domestic issuers. Our directors who were previously designated as external directors, Dr. Avraham Molcho and Mr. Rami Dar, shall continue to serve to serve as "ordinary" (non-external) directors, as Class I directors, until the end of the term of their respective class.

Audit Committee

In accordance with the Relief Regulations described above, on March 25, 2024, our board of directors elected to "opt out" from the Companies Law requirement to appoint external directors and related rules concerning the composition of the audit committee and compensation committee, effective immediately. Under such exemption, among other things, the composition of our audit committee must comply with the requirements of SEC and Nasdaq rules.

The Nasdaq Rules require us to establish an audit committee comprised of at least three members, all of whom must be independent directors under the respective "independence" requirements of the SEC and Nasdaq, each of whom is financially literate and one of whom has accounting or related financial management expertise at senior levels within a company.

Our Audit Committee is currently comprised of Mr. Rami Dar, Dr. Avraham Molcho and Dr. Raphael Hofstein. Mr. Rami Dar serves as the Chairperson of the Audit Committee. Our board of directors has determined that Mr. Rami Dar (Chairperson) qualifies as an audit committee financial expert as defined by the rules of the SEC and Nasdaq. Our board of directors has determined that each member of our audit committee is "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act, which is different from the test for independence of board and committee members under the Nasdaq Rules.

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 work plan of the internal auditor, examining such work plan before its submission to the board of directors and proposing amendments thereto; (iv) examining internal controls and the internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of its 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 of directors 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 (whether or not it is an extraordinary transaction), 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."

Compensation Committee

In accordance with the Relief Regulations described above, on March 25, 2024, our board of directors elected to "opt out" from the Companies Law requirement to appoint external directors and related rules concerning the composition of the audit committee and compensation committee, effective immediately. Under such exemption, among other things, the composition of our compensation committee must comply with the requirements of the Nasdaq Rules.

Under the Nasdaq Rules, we are required to maintain a compensation committee consisting of at least two directors, each of whom is an independent director within the meaning of the Nasdaq Rules.

Our Compensation Committee is currently comprised of Mr. Rami Dar, Dr. Avraham Molcho, Dr. Raphael Hofstein and Dr. B.J Bormann. Dr. Avraham Molcho serves as the Chairperson of our Compensation Committee. Our board of directors has determined that each member of our compensation committee is independent under the Nasdaq Rules, including the additional independence requirements applicable to the members of a compensation committee.

The responsibilities of the compensation committee include the following:

- to make recommendations to the board of directors for its approval of (i) a compensation policy for officer holders, (ii) once every three years whether to extend the then current compensation policy (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years); and (iii) periodic updates to the compensation policy which may be required from time to time. In addition, the compensation committee is required to periodically examine the implementation of the compensation policy; and

- to approve transactions relating to terms of office and employment of company office holders that require the approval of the compensation committee pursuant to the Companies Law (including determining whether the compensation terms of a candidate for chief executive officer of the company need not be brought to approval of the shareholders).

In addition, our Compensation Committee makes recommendations to the board of directors regarding equity compensation issues (with the board also approving the compensation of our executive officers) and administers our share incentive plan.

Compensation Policy

Under the Companies Law, the board of directors of a publicly traded company is required, 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 by a majority vote of the shares present and voting at a shareholders meeting on the matter, subject to a certain special majority requirement, as set forth in the Companies Law, pursuant to which one of the following must be met:

- the majority of the votes voted in favor includes at least a majority of all the votes of shareholders who are not controlling shareholders of the company and shareholders who do not have a personal interest in the compensation policy, present and voting on the matter(excluding abstentions); or

- the total of opposing votes from among the shareholders who are non-controlling shareholders and shareholders who do not have a personal interest in the matter does not exceed 2% of all the voting rights in the company.

Nonetheless, even if the shareholders of the company do not approve the compensation policy, the board of directors of a company may still approve the compensation policy, provided that the compensation committee and, thereafter, the board of directors determine, based on detailed, documented, reasons and after further discussion of the compensation policy, that the approval of the compensation policy in the best interest of the company.

Our current Compensation Policy was approved at the annual general meeting of our shareholders held in 2022. Below is a summary discussion of the main provisions of our Compensation Policy:

The Compensation Policy includes (among other things) 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 executives 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. Under Israeli law, our board of directors has the authority to approve a change in the incentive structure of all executive officers, including the chief executive officer, up to an immaterial amount. The fixed component of compensation remunerates the specific role covered and scope of responsibilities and 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.

Variable components of compensation are determined with an aim at creating maximum alignment between the Compensation Policy and our operating plan and objectives. Variable components of compensation are primarily based on measurable long-term criteria, except that a non-material portion of variable compensation may be based 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 that of the individual office holder. To support the aforementioned principles, we provide two types of variable compensation: short-term - annual bonuses; and long-term - equity compensation.

Annual bonuses are 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 but may not increase the recommended bonus amount by more than 25%.

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, 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 as of 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 (subject to any other approvals required by applicable law).

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 all events, the weight of all the variable components (out of the total compensation amount which is to be granted for any year) will not be greater than 80% for each office holder and may vary from one office holder to the other.

According to the Companies Law, our Compensation Policy provides that in the event of an accounting restatement, we shall be entitled to recover from office holders' bonus compensation granted, earned or vested based on a pre-accounting restatement of our financial results in the amount of the excess over what would have been paid under the accounting restatement, with a three-year look-back period. However, the compensation recovery will not be triggered in the event of a financial restatement required due to changes in applicable financial reporting standards. In addition, in November 2023 we adopted an Executive Officer Clawback Policy in accordance with the rules of the SEC and Nasdaq.

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.

Investment Monitoring Committee

Our board of directors has established an Investment Monitoring Committee which currently consists of the following three members: Mr. Rami Dar; a director, Ms. Mali Zeevi, our Chief Financial Officer; and Mr. Raziel Fried, our Treasurer and Budgetary Control Director. The role 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 meetings 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 relative thereof); 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. The audit committee is required to oversee the activities and to assess the performance of the internal auditor as well as to approve the internal auditor's work plan. 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 care 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, 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, however, obliged to disclose a personal interest and related information if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction (as defined in the Companies Law).

The term personal interest is defined under the Companies Law to include the personal interest of a person in an action or transaction of a company, including the personal interest of such person's relative or the interest of any entity 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 the chief executive officer, but excluding a personal interest stemming solely from the ownership of shares in such entity. A personal interest includes the personal interest of a person for whom the office holder holds a voting proxy and the personal interest of the office holder voting as a proxy, even if the shareholder granting the proxy has no personal interest in the approval of the matter.

Under the Companies Law, an extraordinary transaction 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 or with a third party in which the office holder has a personal interest that is not an extraordinary transaction and an action of an office holder that would otherwise be deemed a breach of duty of loyalty that may have a material impact on a company's profitability, assets or liabilities 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, a company may, under special circumstances, approve the terms of office and employment that are not consistent 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:

- *Executive officers other than the Chief Executive Officer*. A transaction with an office holder in a public company who 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 a compensation policy, 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 a majority of the shares held by non-controlling shareholders and disinterested shareholders who are present and vote on the matter (excluding abstentions), or, alternatively, the total shareholdings of the non-controlling shareholders and disinterested shareholders who vote against the transaction must not represent more than 2% of the voting rights in the company. However, a company's compensation committee and board of directors, may, in special circumstances approve a transaction despite shareholder rejection, provided that the compensation committee and thereafter the board of directors have determined to approve the transaction based on detailed reasoning, after each having re- discussed the terms of office and employment, and taken the shareholder rejection into consideration.

- *Chief Executive Officer*. 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 a compensation policy and (ii) the shareholders of the company have approved the terms by means of the Special Majority Requirements, as detailed above. However, a company's compensation committee and board of directors, may, in special circumstances approve a transaction with a chief executive officer (who is not a director) that is not approved by shareholders despite shareholder rejection, provided that the company's compensation committee and thereafter the board of directors have determined to approve the transaction, based on detailed reasoning, after each having re-discussed the terms of office and employment, and taken the shareholder rejection into consideration. In addition, the compensation committee may exempt from shareholder approval the terms of office and employment of a candidate for the office of chief executive officer where such officer has no relationship with the controlling shareholder or the company, 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. provided that the terms of office and employment are in accordance with the company's compensation policy.

- *Directors*. 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 a compensation policy 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 Israeli Companies Regulations (Relief in Interested Party Transactions), 2000, the terms of office and engagement of a non-executive director are exempt from shareholder approval if the compensation committee and board of directors determined that (i) such terms of office are only for the benefit of the company, or (ii) 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.

With respect to compensation of an officer (including chief executive officer) or director who is also a controlling shareholder, see "— *Disclosure of personal interests of a controlling shareholder and approval of transactions*."

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 thereof 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. The shareholder approval must meet one of the following requirements:

- at least a majority of the shares held by shareholders who have no personal interest in the transaction who are present and 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 are present and 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, in special circumstances, approve terms of office and compensation of a controlling shareholder that 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 with respect to a compensation policy set forth in the Companies Law. Following such approval by the compensation committee and board of directors, shareholder approval would be required by the special majority described above.

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 related circumstances related.

Approval of Significant Private Placements

Under the Companies Law, a significant private placement of securities requires approval by the board of directors and the shareholders by a simple majority. A private placement is considered a significant private placement if it will cause a person to become a controlling shareholder (within the meaning of the Companies Law) or if all of the following conditions are met: (i) the securities issued amount to 20% or more of the company's outstanding voting rights before the issuance; (ii) some or all of the consideration is other than cash or listed securities or the transaction is not on market terms; and (iii) the transaction will increase the relative holdings of a shareholder who holds 5% or more of the company's outstanding share capital or voting rights or that will cause any person to become, as a result of the issuance, a holder of more than 5% of the company's outstanding share capital or voting rights. However, pursuant to the Relief Regulations, the foregoing shareholder approval requirements shall not apply to a company whose shares are listed on a foreign exchange referenced in the second or third addendum to the Israeli Securities Law, 5728-1968, or the Israeli Securities Law, (which include, among others, the NASDAQ Capital Market), if the law of the foreign jurisdiction sets forth requirements regarding the approval of private placements and the company complies with such requirements as they apply to companies incorporated in such foreign jurisdiction.

Duties of shareholders

Under the Companies Law, a shareholder has a duty to act in good faith and in an acceptable manner in exercising its rights and performing its obligations to the company and other shareholders, and must refrain from abusing its power in the company, 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 under the Companies Law.

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, a 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 of fairness 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 pursuant to an undertaking given by the company in advance of an event or following an event, provided a provision authorizing such indemnification is contained in its articles of association:

- monetary liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder (i) 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 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 (such as a criminal penalty) was imposed, it was imposed with respect to an offense that does not require proof of criminal intent and (ii) in connection with a monetary sanction;

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

- expenses incurred by an office holder or certain compensation payments made to an injured party that were instituted against an office holder in connection with an Administrative Procedure under the Israeli Securities Law, including reasonable litigation expenses and reasonable attorneys' fees; and

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf or by a third party or in connection with criminal proceedings in which the office holder was acquitted or as a result of a conviction for an offense that does not require proof of criminal intent.

An "Administrative Procedure" is defined as a procedure pursuant to chapters H3 (Monetary Sanction by the Israeli Securities Authority), H4 (Administrative Enforcement Procedures of the Administrative Enforcement Committee) or I1 (Arrangement to prevent Procedures or Interruption of procedures subject to conditions) to the Israeli Securities Law, which may result in sanctions, including monetary sanctions and certain restrictions on serving as a director or senior officer of a public company for certain periods of time.

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, provided 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 intentional or reckless) conduct of the office holder;

- a financial liability imposed on the office holder in favor of a third party;
- a monetary liability imposed on the office holder in favor of an injured party in an Administrative Procedure pursuant to Section 52(54)(a)(1)(a) of the Israeli Securities Law; and
- expenses, including reasonable litigation expenses and reasonable attorneys' fees, incurred by an office holder in connection with an Administrative Procedure instituted against him or her pursuant to certain provisions of the Israeli Securities Law.

An Israeli company may not indemnify, exculpate 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 for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, monetary sanction or forfeit levied against the office holder.

Under the Companies Law 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, with respect to the chief executive officer and a director, also by the shareholders. See "— Approval of Related Party Transactions under Israeli Law." However, under regulations promulgated under the Companies Law, the insurance of office holders shall not require shareholder approval and may be approved by only the compensation committee, if the engagement terms are determined in accordance with the company's compensation policy, that compensation policy was approved by the shareholders by the same special majority required to approve a compensation policy, and provided that the insurance policy is on market terms and the insurance policy is not likely to materially impact the company's profitability, assets or obligations.

Our Articles of Association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted by law. We have entered into agreements with each of our directors and executive officers exculpating them, to the fullest extent permitted by law, from liability to us for damages caused to us as a result of a breach of duty of care, and undertaking to indemnify them to the fullest extent permitted by law. The indemnification for a monetary liability imposed in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court, is limited to events determined as foreseeable by the board of directors based on our activities, and to an amount determined by the board of directors as reasonable under the circumstances. The maximum indemnification amount for all office holders, cumulatively, for one or more of such events, shall be equal to the higher of (i) 25% of our total shareholders' equity as reflected in our audited annual financial statements for the year preceding the year in which the event for which the indemnity is sought occurred, and (ii) $5 million. The terms of such agreements are consistent with the provisions of our Compensation Policy that was approved by our shareholders in July 2022. However, in the opinion of the SEC, indemnification of office holders for liabilities arising under the Securities Act is against public policy and therefore unenforceable.

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 our current Compensation Policy that was approved by our shareholders in July 2022.

As of the date of this Annual Report on Form 20-F, except as disclosed in Item 8.A below, 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.

D. Employees

As of December 31, 2023, we had 79 employees, 43 of whom are employed in Israel and 36 of whom in the U.S. Of our employees, 15 hold M.D. or Ph.D. degrees.

	December 31,		
	2021	2022	2023
Management and administration	9	12	12
Research and development	27	29	29
Commercialization and business development	2	8	38
Total	38	49	79

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 and/or the Industrialists' Association 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, 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, 2024 of each of our current directors and executive officers individually and as a group. The percentages shown are based on 1,086,589,165 ordinary shares issued and outstanding as of March 15, 2024. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting power or investment power with respect to securities. All ordinary shares subject to options currently exercisable or exercisable into ordinary shares within 60 days of March 15, 2024, and underlying performance stock units ("PSUs") that shall vest within 60 days of March 15, 2024, are deemed to be outstanding and beneficially owned by the shareholder holding such options or PSUs for the purpose of computing the number of shares beneficially owned by such shareholder. Such shares are also deemed outstanding for purposes of computing the percentage ownership of the person holding the option or PSU. They are not, however, deemed to be outstanding and beneficially owned for the purpose of computing the percentage ownership of any other shareholder.

	Number of Ordinary Shares Beneficially Held	Percent of Class
Directors		
Aharon Schwartz[1]	4,784,970	*
B.J. Bormann[2]	1,079,970	*
Rami Dar[3]	630,000	*
Raphael Hofstein[4]	1,079,970	*
Avraham Molcho[5]	1,079,970	*
Sandra Panem[6]	1,079,970	*
Shaoyu Yan	-	
Gal Cohen	-	
Executive officers		
Philip A. Serlin[7]	12,120,645	1.1%
Mali Zeevi[8]	3,348,030	*
Ella Sorani[9]	3,195,930	*
Holly May [10]	3,567,645	*
All directors and executive officers as a group (12 persons)[11]	31,967,100	2.9 %

* Less than 1.0%.

(1) Includes 3,705,000 Ordinary Shares and 1,079,970 Ordinary Shares issuable upon exercise of outstanding options currently exercisable or exercisable within 60 days of March 15, 2024. Does not include 810,000 Ordinary Shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2024.

(2) Includes 1,079,970 Ordinary Shares issuable upon exercise of outstanding options currently exercisable or exercisable within 60 days of March 15, 2024. Does not include 810,000 Ordinary Shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2024.

(3) Includes 630,000 Ordinary Shares issuable upon exercise of outstanding options currently exercisable or exercisable within 60 days of March 15, 2024. Does not include 810,000 Ordinary Shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2024.

(4) Includes 1,079,970 Ordinary Shares issuable upon exercise of outstanding options currently exercisable or exercisable within 60 days of March 15, 2024. Does not include 810,000 Ordinary Shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2024.

(5) Includes 1,079,970 Ordinary Shares issuable upon exercise of outstanding options currently exercisable or exercisable within 60 days of March 15, 2024. Does not include 810,000 Ordinary Shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2024.

(6) Includes 1,079,970 Ordinary Shares issuable upon exercise of outstanding options currently exercisable or exercisable within 60 days of March 15, 2024. Does not include 810,000 Ordinary Shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 15, 2024.

(7) Includes 171,900 Ordinary Shares and 11,948,745 Ordinary Shares issuable upon exercise of outstanding options and PSUs currently exercisable or exercisable within 60 days of March 15, 2024. Does not include 11,996,775 Ordinary Shares issuable upon exercise of outstanding options and PSUs that are not exercisable within 60 days of March 15, 2024.

(8) Includes 328,665 Ordinary Shares and 3,019,365 Ordinary Shares issuable upon exercise of outstanding options and PSUs currently exercisable or exercisable within 60 days of March 15, 2024. Does not include 2,862,840 Ordinary Shares issuable upon exercise of outstanding options and PSUs that are not exercisable within 60 days of March 15, 2024.

(9) Includes 66,150 Ordinary Shares and 3,129,780 Ordinary Shares issuable upon exercise of outstanding options and PSUs currently exercisable or exercisable within 60 days of March 15, 2024. Does not include 2,862,840 Ordinary Shares issuable upon exercise of outstanding options and PSUs that are not exercisable within 60 days of March 15, 2024.

(10) Includes 3,567,645 Ordinary Shares issuable upon exercise of outstanding options and PSUs currently exercisable or exercisable within 60 days of March 15, 2024. Does not include 7,052,865 Ordinary Shares issuable upon exercise of outstanding options and PSUs that are not exercisable within 60 days of March 15, 2024.

(11) See footnotes (1)-(10) for certain information regarding beneficial ownership.

Equity Compensation Plan

2003 Amended and Restated Share Incentive Plan

In 2003, we adopted the BioLineRx Ltd. 2003 Share Incentive Plan, or the Plan. In August 2013, our board of directors approved certain amendments to the Plan and extended the term of the Plan until November 2023, and the Plan was renamed as the BioLineRx Ltd. 2003 Amended and Restated Share Incentive Plan. In January 2016, our board of directors approved amendments to the Plan in order to permit the granting of restricted share units, or RSUs, and PSUs to eligible grantees. In November 2023, our board of directors approved the extension of the term of the Plan for an additional six-month period, until May 2024. References below to the "Plan" refer to the Plan as amended in August 2013, January 2016 and November 2023.

The Plan provides for the granting of options, ordinary shares, RSUs and PSUs 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, 2024, options to purchase 119,786,490 ordinary shares and an aggregate 32,412,375 PSUs were outstanding under the Plan.

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, 2024, 17.7 million ordinary shares were reserved for future issuance under the Plan.

The Plan is administered by our board of directors for the purposes of making equity grants and approving the terms of those grants, including, exercise price (in the case of options), vesting schedule, acceleration of vesting and the other matters necessary in the administration of the Plan. Equity grants made under the Plan to eligible employees and office holders who are Israeli residents are made under Section 102 of the Israeli Income Tax Ordinance [New Version], 5721-1961, or the 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 of grant. Under Section 102 of the Income Tax Ordinance, any tax payable by an employee from the grant of securities or the exercise of options or vesting of RSUs or PSUs is deferred until the transfer of the securities (or ordinary shares issued upon the exercise of options or the vesting of RSUs or PSUs) 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 and RSUs granted under the Plan generally vest over four years. Options generally expire 10 years from the grant date. If we terminate an employee's employment or service for cause, all of the grantee's vested and unvested equity awards expire immediately from the time of delivery of the notice of discharge, unless determined otherwise by the compensation committee or the board of directors. Upon termination of employment or service for any other reason other than for cause, vested options may be exercised within three months of the termination date or if termination of employment or service is due to death or disability of the employee, but in no event after the expiration date of the awards, within 12 months following such death or disability, in each case unless otherwise determined by the compensation committee or the board of directors. Vested options which are not exercised and unvested options, RSUs or PSUs return to the pool of reserved ordinary shares under the Plan for future grants. The right to receive ordinary shares pursuant to PSUs granted under the Plan will vest upon the achievement 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.

F. Disclosure of a registrant's action to recover erroneously awarded compensation.

There was no erroneously awarded compensation that was required to be recovered pursuant to the BioLineRx Ld. Executive Officer Clawback Policy during the fiscal year ended December 31, 2023.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our shares as of March 15, 2024, by each person or entity known by us to own beneficially more than 5% of our ordinary shares. The percentages shown are based on 1,086,589,165 ordinary shares issued and outstanding as of March 15, 2024.

Name	Number of Ordinary Shares Beneficially Held	Percent of Class
Hong Seng Technology Limited[1]	102,437,055	9.4%

(1) Based on Schedule 13D filed with the SEC on October 26, 2023. According to the Schedule 13D, includes 6,829,137 ADS, representing 102,437,055 ordinary shares held by Hong Seng Technology Limited. Lepu (Hong Kong) Co., Limited holds 66.67% equity interest of Hong Seng Technology Limited. Lepu Holdings Limited holds 99.5% equity interest of Lepu (Hong Kong) Co., Limited. Lepu Medical (Europe) Cooperatief U.A. holds 100% equity interest of Lepu Holdings Limited. Lepu Medical Technology (Beijing) Co., Ltd. holds 99.95% equity interest of Lepu Medical (Europe) Cooperatief U.A. Lepu Medical Technology (Beijing) Co., Ltd. is a company publicly listed on Shenzhen Stock Exchange in the PRC (300003.SZ).

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, 2021.

None of our shareholders has different voting rights from other shareholders. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

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, 2024, BNY held 993,504,176 ordinary shares representing 91% 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.

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 — 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 law. We have entered into agreements with each of our office holders exculpating them, to the fullest extent permitted by law, from liability to us for damages caused to us as a result of a breach of duty of care, and undertaking to indemnify them to the fullest extent permitted by law, to the extent that these liabilities are not covered by insurance. We have obtained directors' and officers' liability insurance for each of our officers and directors. See "Item 6. C — Directors, Senior Management and Employees — Board Practices — Exculpation, insurance and indemnification of office holders."

GSAP Agreement

On February 9, 2023, we entered into an agreement with GSAP Biomed Ltd., or GSAP, pursuant to which GSAP undertook to provide ongoing quality assurance support services to us. This agreement was terminated effective January 1, 2024. Rami Dar, one of our directors (who formerly served as an external director, within the meaning of the Companies Law), who serves as the chairman of our audit committee and as a member of our compensation committee and investment monitoring committee, is a non-executive chairman of Novolog Ltd., which is the parent company of GSAP. During 2023, we paid GSAP NIS 408,000 (approximately $110,000) as compensation for the services provided thereunder.

Gloria License Agreement and Securities Purchase Agreement

On August 27, 2023, we entered into the License Agreement with HST and Gloria, collectively, the Purchaser Party,, pursuant to which we granted HST an exclusive, royalty-bearing, sublicensable license with respect to the intellectual property rights and know-how associated with motixafortide in order to develop and commercialize motixafortide in Asia (other than Israel and certain other countries) and to engage and authorize Gloria to perform services under the License Agreement in such territory. In connection with the License Agreement, on August 27, 2023, we also entered into a securities purchase agreement with HST and Gloria pursuant to which we agreed to sell and issue to HST, in a private placement, an aggregate of 6,829,137 of our ADSs. Aggregate gross proceeds from the sale were approximately $14.6 million. In connection with the closing of the private placement, Dr. Shaoyu Yan, a nominee of HST, was appointed to our board of directors to serve as one of our Class III directors until our annual general meeting of shareholders to be held in 2026. The appointment was made effective in November 2023. In addition, effective as of the annual general meeting to be held in 2026 and for so long as the Purchaser Party is the owner of at least 5% of our issued and outstanding ordinary shares, the Purchaser Party shall have the right, but not the obligation, to nominate one person for election by our shareholders to serve as a member of our board of directors, provided that such nominee provides the requisite certifications required for appointment as a director of a public company under Israeli law.

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

On January 5, 2023, a putative securities class action complaint captioned Winston Peete v. BioLineRx Ltd. and Philip A. Serlin (Case no: Case 2:23-cv-00041 was filed in the U.S. District Court for the District of New Jersey by purported shareholder Winston Peete, naming us and our chief executive officer, Mr. Serlin, as defendants. The complaint asserts violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, claiming that the defendants made false and materially misleading statements and failed to disclose material adverse facts pertaining to our financial position with regard to the development of motixafortide and that we would require a loan and a securities offering to commercialize motixafortide. The complaint asserts a putative class period of February 23, 2021 to September 19, 2022, inclusive and seeks certification as a class action and an unspecified amount of damages. On July 5, 2023, plaintiffs filed an amended complaint alleging the same claims and adding the Company's Chief Financial Officer, Mali Zeevi, as a defendant. On September 5, 2023, defendants filed a motion to dismiss the amended complaint in its entirety. The motion has been fully briefed and is sub judice. In addition, on February 5, 2023, we received a lawsuit and motion to approve the lawsuit as a class action lawsuit pursuant to the Class Action Lawsuits Law 5766-2006 which was filed against us and Mr. Serlin in the Tel Aviv District Court (Economic Division). The motion asserts substantially similar allegations as the U.S. action described above. The motion asserts to define the class as all shareholders who held the company's securities traded on the TASE, on September 19, 2022 and the class period relates to the company's statements between February 23, 2021, and September 19, 2022. The total amount claimed, if the lawsuit is certified as a class action, as set forth in the motion is approximately NIS 113.5 million (approximately $32 million). The outcome of both legal proceedings is uncertain at this point. Based on an initial evaluation of the lawsuits, we believe that they are without merit and intend to vigorously defend ourselves against such actions.

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. Israeli law limits the distribution of cash dividends to the greater of retained earnings or earnings generated over the two most recent years (referred to as the "profit test"), in either case provided that we reasonably believe that the dividend will not render us unable to meet our existing and foreseeable obligations when due (referred to as the "solvency test"). Notwithstanding the foregoing, in the event that a company does meet the profit test, dividends may be paid with the approval of a court, provided that the court is convinced that the company meets the solvency test. However, in accordance with the Relief Regulations, as a company whose shares are listed on a foreign exchange referenced in the second or third addendum to the Israeli Securities Law (which include, among others, the NASDAQ Capital Market), our board of directors may resolve to distribute a dividend by way of a share repurchase program if the company does not meet the profit test without seeking the approval of the court, subject to the following: (i) the company meets the solvency test; and (ii) we provide a notice to certain creditors regarding our intention to distribute a dividend by way of a share repurchase program in accordance with the notice requirements set forth in the Relief Regulations and no such creditor submits an objection within 30 days of the notice (otherwise, court approval would be required for such distribution in accordance with the requirements of the Companies Law). For information regarding taxation of dividends, see "Item 10E. Additional Information — Taxation — Israeli Tax Considerations."

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 set forth 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.

Board of Directors

See "Item 6. Directors, Senior Management and Employees — C. Board Practices."

Borrowing Powers

Pursuant to the Companies Law and our Articles of Association, our board of directors may exercise all powers and take all actions that are not required under law or under our Articles of Association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

Shareholder Meetings

Under the Companies Law, annual general meetings of shareholders are required to be held at least once in every calendar year (within 15 months after the last preceding annual general meeting of shareholders). All general meetings other than the annual meeting of shareholders are referred to in our Articles of Association as extraordinary meetings.

The Companies Law provides that an extraordinary general meeting of shareholders may be called by the board of directors as it deems fit. In addition, the board of directors is required to convene an extraordinary general meeting of shareholders upon the written request of (i) two or more directors or 25% of the directors in office, or (ii) one or more shareholders holding, in the aggregate, at least (a) 5% of the issued share capital and 1% of the voting rights; or (b) 5% of the voting rights of the company. However, pursuant to the Relief Regulations, in the case of a company whose shares are listed on a foreign exchange referenced in the second or third addendum to the Israeli Securities Law (which include, among others, the NASDAQ Capital Market, such as us), the board of directors shall convene an extraordinary meeting of shareholders upon the written request of one or more shareholders holding, in the aggregate, at least (a) 10% of the issued share capital and 1% of the voting rights; or (b) 10% of the voting rights of the company, provided that if the law of the foreign jurisdiction, as it applies to companies incorporated in such jurisdiction, permit a shareholder holding less than 10% of the issued share capital or voting rights to request to convene such a shareholder meeting, the Relief Regulations shall not apply.

The Companies Law requires that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our Articles of Association;
- appointment, termination or the terms of service of our auditors;
- appointment of external directors (if applicable);
- approval of certain related party transactions;
- increases or reductions of our authorized share capital;
- a merger; and
- the exercise of our board of directors' powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management.

Shareholders entitled to participate and vote at our general meetings are the shareholders of record on a date to be determined by the board of directors, which, according to the Relief Regulations, as a company listed on certain exchanges outside Israel (including the Nasdaq Capital Market), may be between 4 and 60 days prior to the date of the meeting.

Under the Companies Law, shareholder meetings generally require prior notice of not less than 21 days or, with respect to certain matters, such as election of directors and affiliated party transactions, not less than 35 days. Only shareholders of record as reflected on our share register at the close of business on the date fixed by the board of directors as the record date determining the then shareholders who will be entitled to vote, shall be entitled to notice of, and to vote, in person or by proxy, at a general meeting and any postponement or adjournment thereof.

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.

Gloria License Agreement and Securities Purchase Agreement

On August 27, 2023, we entered into the License Agreement with HST and Gloria, pursuant to which we granted HST an exclusive, royalty-bearing, sublicensable license with respect to the intellectual property rights and know-how associated with motixafortide in order to develop and commercialize motixafortide in the Territory and to engage and authorize Gloria to perform services under the License Agreement in the Territory.

Pursuant to the terms of the License Agreement, the Licensee made a $15 million upfront payment in October 2023, upon the closing of the transaction. We are entitled to up to $49 million based on the achievement of certain development and regulatory milestones in China and Japan, and up to $197 million in sales milestones based on defined sales targets of motixafortide in the Territory. Additionally, we are eligible to receive tiered, double-digit royalties (ranging from 10-20%), on aggregate net sales of motixafortide in the Territory payable on a country-by-country basis until the longer of (i) fifteen years from the date of the first sale of motixafortide by Licensee, (ii) the last to expire valid claim of any licensed patents with respect to motixafortide in such country and (iii) the expiration of motixafortide's orphan drug status in such country. The royalties payable by Licensee to us are to be reduced by 50% following the end of the initial royalty term and to also be reduced upon the occurrence of certain events, including, on a country-by-country basis, the entry of a generic product in such country.

In connection with the License Agreement, on August 27, 2023, we also entered into a securities purchase agreement with HST and Gloria pursuant to which we agreed to sell and issue to HST in a private placement an aggregate of 6,829,137 of our ADSs at a price of $2.136 per ADS. Aggregate gross proceeds from the sale were approximately $14.6 million. The private placement closed in October 2023. In connection with the closing of the private placement, Dr. Shaoyu Yan, a nominee of HST, was appointed by our board of directors to serve as one of our Class III directors until our annual general meeting of shareholders to be held in 2026. The appointment was made effective in November 2023. In addition, effective as of the 2026 annual general meeting and for so long as the Purchaser Party is the owner of at least 5% of our issued and outstanding ordinary shares, the Purchaser Party shall have the right, but not the obligation, to nominate one person for election by our shareholders to serve as a member of our board of directors, provided that such nominee provides the requisite certifications required for appointment as a director of a public company under Israeli law.

The License Agreement includes various development obligations for the Licensee pursuant to an agreed-upon development plan, including the execution of a registrational study in stem-cell mobilization and the execution of a randomized Phase 2b study in first-line pancreatic adenocarcinoma.

Loan Agreements 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 bore 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. In September 2022, this loan was repaid in full.

In September 2022, we entered into a new loan agreement with Kreos Capital, or the Loan Agreement. Under the Loan Agreement, Kreos Capital will provide us with access to term loans in an aggregate principal amount of up to $40 million in three tranches as follows: (a) a loan in the aggregate principal amount of up to $10 million, available for drawdown upon closing of the Loan Agreement and until April 1, 2023, or Tranche A, (b) a loan in the aggregate principal amount of up to $20 million, available for drawdown upon achievement of certain milestones and until April 1, 2024, or Tranche B, and (c) a loan in the aggregate principal amount of up to $10 million, available for drawdown upon achievement of certain milestones and until October 1, 2024, or Tranche C and together with Tranche A and Tranche B, the Loans. We drew down the initial tranche of $10 million following execution of the agreement in September 2022.

We intend to use the proceeds of the Loans, together with cash on-hand, to facilitate the commercial launch of motixafortide in autologous stem cell mobilization for multiple myeloma patients, as well as for general corporate purposes.

Until July 1, 2023, Tranche A is payable on an interest-only basis, and thereafter in up to 36 equal monthly payments of principal and interest accrued thereon, subject to extension of the interest-only payment period if certain milestones are met, with a corresponding reduction in the principal and interest payment period through July 1, 2026. Until July 1, 2024, Tranche B is payable on an interest-only basis, and thereafter in up to 36 equal monthly payments of principal and interest accrued thereon, subject to extension of the interest-only payment period if certain milestones are met, with a corresponding reduction in the principal and interest payment period through July 1, 2027. Until January 1, 2025, Tranche C is payable on an interest-only basis, and thereafter in up to 30 equal monthly payments of principal and interest accrued thereon, subject to extension of the interest-only payment period if certain milestones are met, with a corresponding reduction in the principal and interest payment period through July 1, 2027.

Interest on each tranche of the Loans accrues at a fixed rate of 9.5% per annum from the drawdown date until repayment in full of the tranche. In addition, the Lender will be entitled to mid-to-high single-digit royalties on motixafortide sales for stem cell mobilization, up to a total maximum aggregate of $13.5 million.

We may prepay all, but not less than all, of the outstanding balance of any of the Loans. In case of prepayment within 12 months of a drawdown, we will pay a sum equal to (i) the principal balance then outstanding, and (ii) an aggregate of all remaining interest payments that would have been paid on the Loans throughout the remainder of the term of the Loan, discounted back at the secured overnight financing rate administered by the Federal Reserve Bank of New York. In case of prepayment within 13-24 months of the effective date of the Loan Agreement, we will pay a sum equal to 102% of principal balance then outstanding. In case of prepayment within 25-36 months of the effective date of the Loan Agreement, we will pay a sum equal to 101% of the principal balance then outstanding. In connection with any prepayment, we will also pay an end of loan payment equal to 5% of the amount of each tranche drawn down upon the final repayment of each such tranche, or the End of Loan Payment, and any other unpaid fees or costs, if any. In addition, if we prepay the Loans in the first 24 months from the first drawdown and, in the event that the combined cash return to Kreos Capital from the drawn down Loans under the Loan Agreement, including prepayment amounts and any revenue based payments, or the Combined Loan Cash Economics, do not reach 1.3 times the aggregate amount of drawn down Loans, or the Minimum Cash Return Amount, we shall pay Kreos Capital an additional cash amount equal to the difference between the Combined Loan Cash Economics paid or payable and the Minimum Cash Return Amount.

The Loans are subject to mandatory accelerated repayment provisions that require repayment of the outstanding principal amount of the Loans, and all accrued and unpaid interest thereon, upon the occurrence of an event of default, subject to certain limitations and cure rights. In addition, in the event of acceleration upon an event of default (a) we will be required to pay the aggregate of the monthly interest payments scheduled to be paid by the Company for the period from the date of acceleration to the expiry of the applicable Loan, in each case discounted from the applicable monthly repayment date to the date of prepayment at the rate of 2% per annum and (b) the End of Loan Payment.

In connection with entering into the Loan Agreement, we agreed to pay the Lender a fee of up to $30,000 plus value-added-tax for legal and other ancillary fees. Pursuant to the Loan Agreement, upon the execution of the agreement, we agreed to pay Kreos Capital a transaction fee equal to $500,000, and, upon the drawdown of each tranche of the Loans, we shall pay Kreos Capital an advance payment of the last month's payment of principal and interest for such tranche. Additionally, we will be required to pay an End of Loan Payment.

Outstanding borrowings under the Loan Agreement are secured by (a) a first priority fixed charge over certain assets and intellectual property of the Company as well as all shares held by the Company in BioLineRx USA, Inc, or the Fixed Charge, (b) a first priority floating charge over all our assets as of the date of the Loan Agreement or thereafter acquired, other than the assets charged under the Fixed Charge or as otherwise specifically excluded pursuant to the terms of the floating charge, and (c) subject to the provisions of the Fixed Charge, a security interest in our intellectual property.

The Loan Agreement contains customary representations and warranties, indemnification provisions in favor of the Lender, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict the Company's ability to, among other things, incur additional indebtedness, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, and dispose of assets, in each case subject to certain exceptions. In addition, the Company is required to maintain a cash balance of at least $10 million. The Company has also granted Kreos Capital certain information rights.

D. Exchange Controls

There are currently no Israeli governmental laws, decrees or regulations that restrict or affect our import or export of capital, including the availability of cash and cash equivalents for use by us and our wholly owned subsidiaries, or the remittance of dividends, interest or other payments to non-resident holders of our securities, except for shareholders who are subjects of countries that are, or have been, in a state of war with Israel 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. To the extent that this discussion is 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. The discussion below is subject to change, including due to amendments under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which change could affect the tax consequences described below.

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.

As of December 31, 2023, the tax loss carryforwards of BioLineRx were approximately $304 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 a pro-rata distribution of 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 the Income Tax Ordinance and/or regulations promulgated thereunder or under 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 (the "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 or exchange of any capital assets by residents of Israel, as defined for Israeli tax purposes, and on the sale or exchange of assets located in Israel, including shares in Israeli companies, by non-residents of Israel, unless a specific exemption is available pursuant to the Income Tax Ordinance or the regulations thereunder 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. The inflationary surplus is generally exempt from tax.

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.

Real capital gains derived by an Israeli company are generally subject to tax at the same rate as the corporate tax rate (currently 23%).

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 Treaty, the sale, exchange or disposition of our ordinary shares by a shareholder who is a U.S. resident (for purposes of the 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 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 Treaty does not cover 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 (or within 30 days of the sale if the seller is not otherwise required to file a tax return in Israel). However, if all tax due was withheld at source according to applicable provisions of the 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 698,280 for 2023 and NIS 721,560 for 2024 (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, the Treaty, 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, grantor trusts, persons who acquire our ordinary shares through the exercise or cancellation of employee stock options or otherwise as compensation for their services, 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, 2024, and it is possible that we will be a PFIC for the taxable year ending December 31, 2024 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 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.

As a result of recent changes to the U.S. foreign tax credit rules, a withholding tax generally will need to satisfy certain additional requirements in orders to be considered a creditable tax for a U.S. investor. We have not determined whether these requirements have been met and, accordingly, no assurance can be given that any withholding tax on dividends paid by us will be creditable. 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 2023 taxable year and have not determined whether we will be a PFIC for our 2024 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 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, 2021, 2022 and 2023, and we have not determined whether we will be a PFIC for the taxable year ending December 31, 2024. 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, 2024 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 generally are required to file annual tax returns (including on IRS Form 8621) containing such information as the U.S. Treasury requires (whether or not a mark-to-market election is or has been made). 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. Failure to file IRS Form 8621 for each applicable taxable year may result in substantial penalties and the statute of limitations on the assessment and collection of U.S. federal income taxes of such U.S. Investor for the related taxable year may not close until three years after the date on which the required information is filed. 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.

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 Israeli Securities Law 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.

J. Annual Report to Security Holders

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURE ON MARKET RISK

Our consolidated financial statements are prepared in conformity with IFRS, as issued by the IASB. We are exposed to a variety of risks in the ordinary course of our business, including, but not limited to, interest rate risk, foreign exchange risk, liquidity risk and credit risk, as discussed below. We regularly assess each of these risks to minimize any adverse effects on our business as a result of those factors. See Note 3 to our consolidated financial statements, which are included elsewhere in this Annual Report, for further discussion of our exposure to these risks.

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 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 Chief Executive Officer, or the CEO, and the Chief Financial Officer, or the CFO, have 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, 2023.

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.

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, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERTS

Our board of directors has determined that Mr. Rami Dar is the audit committee financial expert. Mr. Dar 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,	
	2022	**2023**
Services Rendered	*(in thousands of U.S. dollars)*	
Audit Fees(1)	130	130
Audit-Related Fees(2)	4	17
Tax Fees(3)	18	52
All Other Fees	-	-
Total	152	199

(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

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 have elected to follow the provisions of the Companies Law, rather than the Nasdaq Rules, with respect to the following requirements:

- *Distribution of periodic reports to shareholders*. Under Israeli law, a public company whose shares are traded on the TASE, is not required to distribute periodic 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 a public website. We will only mail such reports to shareholders upon request. In addition, we make our audited financial statements available to our shareholders at our offices.

- *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, as permitted under the Companies Law, 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 (and, with respect to an adjourned meeting, a quorum consists of any number of shareholders present in person or by proxy).

- *Nomination of Directors*. We follow Israeli corporate governance practices instead of the requirements of the Nasdaq Rules with regard to the nomination committee and director nomination procedures. Israeli law and practice does not require director nominations to be made by a nominating committee of our board of directors consisting solely of independent directors, as required under the Nasdaq Rules. In accordance with Israeli law and practice, directors are recommended by our board of directors for election by our shareholders (other than directors elected by our board of directors to fill a vacancy), and certain of our shareholders may nominate candidates for election as directors by the general meeting of shareholders in accordance with the Companies Law and our Articles of Association.

- *Compensation of Officers*. We follow Israeli law and practice with respect to the approval of officer compensation, 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, generally require the approval of the compensation committee, the board of directors and under certain circumstances (such as if the officer is a director or controlling shareholder) the shareholders, either in accordance with our compensation policy or, in special circumstances in deviation therefrom, taking into account certain considerations set forth in the Companies Law. See "Item 6.C— Directors, Senior Management and Employees — Board Practices — Compensation Committee" for information regarding the Compensation Committee, and "Item 6.C — Directors, Senior Management and Employees — Approval of Related Party Transactions under Israeli Law" for information regarding the approvals required with respect to approval of terms of office and employment of office holders, pursuant to the Companies Law.

- *Approval of Related Party Transactions*. We follow Israeli law and practice with respect to the approval of interested party acts and transactions, as set forth in sections 268 to 275 of the Companies Law, and the regulations promulgated thereunder, which generally require the approval of the audit committee, the board of directors and, under certain circumstances (such as if the officer holder is a controlling shareholder) the shareholders, as may be applicable, for specified transactions. See "Item 6.C— Directors, Senior Management and Employees —Board Practices — Approval of Related Party Transactions under Israeli Law" for information regarding the approvals required with respect to approval of related party transactions pursuant to the Companies Law.

- *Shareholder Approval*. We intend to 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 and practice. However, any equity-based compensation arrangement with a director or the chief executive officer or the material amendment of such an arrangement must be approved by our Compensation Committee, board of directors and shareholders, in that order.

Except as stated above, we currently intend to comply with the rules generally applicable to U.S. domestic companies listed on Nasdaq. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq corporate governance rules. Following our home country governance practices, as opposed to the requirements that would otherwise apply to a company listed on Nasdaq, may provide less protection than is accorded to investors under Nasdaq listing requirements applicable to domestic issuers. For more information, see "Item 3.D — Key Information - Risks Related to 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.*"

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

Pursuant to applicable SEC transition guidance, the disclosure required by Item 16J will only be applicable to the Company from the fiscal year ending on December 31, 2024.

ITEM 16K. CYBERSECURITY

Risk management and strategy

We have developed and maintain a cybersecurity risk management program that focuses primarily on securing and safeguarding computer systems, networks, cloud services, business applications, and data and that is integrated in our overall risk management strategy and framework. We have implemented protocols to protect against cyber threats and ensure the containment and security of sensitive business data, including ongoing security reviews of critical systems, continuous monitoring of event data, and employee training programs, which processes are aligned with our overall business and operational goals and strategies. Our risk assessment occurs on an ongoing basis and covers identification of risks that could act against the company's objectives as well as specific risks related to a compromise to the security of data.

We engage a third-party to provide operational support for cybersecurity risks. This forms a critical part of our risk management strategy, facilitating effective management and mitigation of risks, and ensuring adherence to applicable regulatory and industry standards.

Overall, we believe that we have established a robust framework for confidentiality, integrity, and availability of information, adhering to relevant security standards, practices, and compliance requirements. In addition, we maintain insurance to help protect against risks associated with cybersecurity threats. As of the date of this report, we do not believe that any risks from cybersecurity threats have materially affected, or are reasonably likely to materially affect, us, including our business strategy, results of operations, or financial condition. However, despite our efforts, we cannot eliminate all risks from cybersecurity threats, or provide assurances that we have not experienced an undetected cybersecurity incident. For more information about these risks, please see "Item 3.D. Key Information — Risk Factors – Risks Related to Our Industry – Significant disruptions of our information technology systems or breaches of our data security could adversely affect our business." in this Annual Report.

Governance

Our audit committee provides oversight of our cybersecurity program and helps guide our strategy for managing cybersecurity risks in the context of our overall risk management system. Our cybersecurity program is managed by our Chief Financial Officer and our internal IT team who is responsible for leading enterprise-wide cybersecurity strategy, protocols, framework, standards and processes. The Chief Financial Officer reports to our board of directors, as well as our Chief Executive Officer and other members of senior management as appropriate.

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	Articles of Association, as amended August 7, 2023
2.2 *	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(2)	Employment Agreement with Ella Sorani, dated January 11, 2017
4.6(1)	Amendment to Employment Agreement between BioLineRx Ltd and Ella Sorani, dated September 24, 2020
4.7†(4)	License Agreement entered into as of November 25, 2007 between BioLine Innovations Jerusalem L.P. and Innovative Pharmaceutical Concepts, Inc.
4.8(5)	BioLineRx Ltd. Amended and Restated 2003 Share Incentive Plan
4.9(6)	License Agreement entered into as of September 2, 2012 by and between the Registrant and Biokine Therapeutics Ltd.
4.10(7)†	Amendment Agreement entered into as of October 2, 2018 by and between the Registrant and Biokine Therapeutics Ltd.
4.11(7)	Warrant issued to Kreos Capital V dated October 2, 2018
4.12(8)	Compensation Policy for Executives and directors, as amended
4.13(10)	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)
4.14(11)†	License Agreement entered into as of December 22, 2014 between the Registrant and Wartner Europe BV
4.15†	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.
4.16(3)†	Amended and Restated Exclusive License Agreement entered into as of April 30, 2013 between the University of Massachusetts and Agalimmune Ltd.
4.17†	Patent and Know-how License Agreement entered into as of September 19, 2017 between Kode Biotech Limited and Agalimmune Ltd.
4.18†	Second Amendment Agreement entered into as of October 16, 2018 between the University of Massachusetts and Agalimmune Ltd.
4.19†	Amendment No. 1 to License Agreement entered into as of June 18, 2018 between the Registrant and Wartner Europe BV
4.20(9)	First Addendum to License Agreement entered into as of October 16, 2019 by and between the Registrant and Biokine Therapeutics Ltd., as amended.

4.21[12]	Form of Warrant issued February 7, 2019
4.22[13]	Form of Underwriter Warrant to be issued by BioLineRx Ltd. on January 22, 2021
4.23[14]	At-the-Market Sales Agreement, dated September 3, 2021, between BioLineRx Ltd. and H.C. Wainwright & Co., LLC
4.24[15]	Agreement for the Provision of a Loan Facility entered into as of September 14, 2022, by and between the Registrant and Kreos Capital VII Aggregator SCSP
4.25[16]	Form of Securities Purchase Agreement dated as of September 18, 2022 between the Registrant and the investors listed therein
4.26[16]	Form of Warrant issued by the Registrant on September 21, 2022
4.27[16]	Form of Placement Agent Warrant issued by the Registrant on September 21, 2022
4.28[18]†	License Agreement dated as of August 27, 2023 between the BioLineRx Ltd., Guangzhou Gloria Biosciences Co., Ltd. and Hong Seng Technology Limited
4.29[18]†	Securities Purchase Agreement dated as of August 27, 2023 between the BioLineRx Ltd., Hong Seng Technology Limited and Guangzhou Gloria Biosciences Co., Ltd.
8.1[17]	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
97.1*	BioLineRx Ltd. Executive Officer Clawback Policy
101	The following financial information from BioLineRx Ltd.'s Annual Report on Form 20-F for the fiscal year ended December 31, 2023 formatted in Inline XBRL (Extensible Business Reporting Language): (i) Consolidated Statements of Financial Position at December 31, 2023 and 2022; (ii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2023, 2022 and 2021; (iii) Statements of Changes in Equity for the years ended December 31, 2023, 2022 and 2021; (iv) Consolidated Cash Flow Statements for the years ended December 31, 2023, 2022 and 2021; and (v) Notes to the Consolidated Financial Statements.

* Filed herewith.

† 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 Form 6-K filed on May 27, 2022.

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

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

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

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

(13) Incorporated by reference to the Registrant's Form 6-K filed on January 21, 2021.

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

(15) Incorporated by reference to the Registrant's Form 6-K filed on September 15, 2022.

(16) Incorporated by reference to the Registrant's Form 6-K filed on September 21, 2022.

(17) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 16, 2022.

(18) Incorporated by reference to the Registrant's Form 6-K filed on August 30, 2023.

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 26, 2024

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, 2023 and 2022, 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, 2023, 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, 2023, 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, 2023 and 2022 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 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, 2023, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1(c) to the consolidated financial statements, the Company has suffered recurring losses from operations and has cash outflows from operating activities that indicate that a material uncertainty exists that may cast significant doubt (or raise substantial doubt as contemplated by PCAOB standards) about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1(c). The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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. 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.

Revenue Recognition and Determination of Standalone Selling Price – License Agreement with Hong Seng Technology Limited ("HST") and Guangzhou Gloria Biosciences Co., Ltd. ("Gloria")

As discussed in Note 16 to the consolidated financial statements, the Company entered into a license agreement (the "License Agreement") with HST and Gloria during the year ended December 31, 2023. The Company recognized revenue of $4.6 million (for the year ended December 31, 2023) and contract liabilities of $12.9 million (as of December 31, 2023) related to the License Agreement. The Company's performance obligations under the License Agreement include: (i) a stem-cell mobilization ("SCM") license, (ii) support services related to SCM and (iii) a pancreatic adenocarcinoma ("PDAC") license and support services. The Company determined the estimated standalone selling prices of the SCM license and the PDAC combined performance obligation using price offers for each indication with the assistance of a valuation specialist and determined the estimated standalone selling price of the support services for SCM using cost-plus margin. The Company recognized revenue from the SCM license at point of time and recognized revenue from the SCM support services and the PDAC license and support services over time using the input method based on a ratio between the support hours incurred to the total hours expected to be incurred until satisfying the performance obligation.

The principal considerations for our determination that performing procedures relating to the determination of the standalone selling price and revenue recognition – estimated hours to complete PDAC license and support services performance obligation is a critical audit matter are there was significant judgment and estimation used by management. This in turn led to a significant 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 revenue recognition process including controls over the determination of estimated standalone selling prices and the estimated hours to complete the PDAC license and support services performance obligation. The procedures also included, among others, (i) reading the related agreements; (ii) evaluating and testing management's process for determining the estimated standalone selling prices and the estimated hours to complete the PDAC license and support services performance obligation which included evaluating the reasonableness of the valuation methodology and significant assumptions, including the estimated expected support hours, used by management and considering the factors that can affect the accuracy of those estimates. Professionals with specialized skill and knowledge were used to assist in the evaluation of the Company's model.

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

Tel Aviv, Israel
March 26, 2024

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

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31,	
		2022	2023
		in USD thousands	
Assets			
CURRENT ASSETS			
Cash and cash equivalents	5	10,587	4,255
Short-term bank deposits	6	40,495	38,739
Trade receivables		-	358
Prepaid expenses		198	1,048
Other receivables	18a	721	830
Inventory	7	-	1,953
Total current assets		52,001	47,183
NON-CURRENT ASSETS			
Property and equipment, net	8	726	473
Right-of-use assets, net	10	1,772	1,415
Intangible assets, net	9	21,885	14,854
Total non-current assets		24,383	16,742
Total assets		76,384	63,925
Liabilities and equity			
CURRENT LIABILITIES			
Current maturities of long-term loans	11	1,542	3,145
Contract liabilities	16	-	12,957
Accounts payable and accruals:			
Trade	18b	6,966	10,869
Other	18b	1,744	3,353
Current maturities of lease liabilities	10	427	528
Total current liabilities		10,679	30,852
NON-CURRENT LIABILITIES			
Warrants	12c	4,509	11,932
Long-term loans, net of current maturities	11	8,626	6,628
Lease liabilities	10	1,729	1,290
Total non-current liabilities		14,864	19,850
COMMITMENTS AND CONTINGENT LIABILITIES	15	-	-
Total liabilities		25,543	50,702
EQUITY	12		
Ordinary shares		27,100	31,355
Share premium		338,976	355,482
Warrants		1,408	1,408
Capital reserve		14,765	17,000
Other comprehensive loss		(1,416)	(1,416)
Accumulated deficit		(329,992)	(390,606)
Total equity		50,841	13,223
Total liabilities and equity		76,384	63,925

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

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year ended December 31,		
		2021	2022	2023
		in USD thousands		
REVENUES	18c	-	-	4,800
COST OF REVENUES	18d	-	-	(3,692)
GROSS PROFIT		-	-	1,108
RESEARCH AND DEVELOPMENT EXPENSES	18e	(19,466)	(17,629)	(12,519)
SALES AND MARKETING EXPENSES	18f	(1,003)	(6,462)	(25,270)
GENERAL AND ADMINISTRATIVE EXPENSES	18g	(4,308)	(5,066)	(6,310)
IMPAIRMENT OF INTANGIBLE ASSETS	9	-	-	(6,703)
OPERATING LOSS		(24,777)	(29,157)	(49,694)
NON-OPERATING INCOME (EXPENSES), NET	18h	(1,830)	5,670	(10,819)
FINANCIAL INCOME	18i	559	694	2,068
FINANCIAL EXPENSES	18j	(1,006)	(2,158)	(2,169)
LOSS AND COMPREHENSIVE LOSS		(27,054)	(24,951)	(60,614)
		in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	14	(0.04)	(0.03)	(0.06)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	14	662,933,695	773,956,973	963,365,525

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, 2021	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 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
CHANGES IN 2022:							
Issuance of share capital and warrants, net	6,029	(1,007)	433	-	-	-	5,455
Employee stock options exercised	5	14	-	(14)	-	-	5
Employee stock options expired	-	623	-	(623)	-	-	-
Share-based compensation	-	-	-	2,245	-	-	2,245
Comprehensive loss for the year	-	-	-		-	(24,951)	(24,951)
BALANCE AT DECEMBER 31, 2022	27,100	338,976	1,408	14,765	(1,416)	(329,992)	50,841
CHANGES IN 2023:							
Issuance of share capital, net	3,242	10,847	-	-	-	-	14,089
Warrants exercised	1,000	5,559	-	-	-	-	6,559
Employee stock options exercised	13	45	-	(31)	-	-	27
Employee stock options expired	-	55	-	(55)	-	-	-
Share-based compensation	-	-	-	2,321	-	-	2,321
Comprehensive loss for the year	-	-	-	-	-	(60,614)	(60,614)
BALANCE AT DECEMBER 31, 2023	31,355	355,482	1,408	17,000	(1,416)	(390,606)	13,223

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

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2021	2022	2023
	in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES			
Loss	(27,054)	(24,951)	(60,614)
Adjustments required to reflect net cash used in operating activities (see appendix below)	3,481	(1,289)	38,006
Net cash used in operating activities	(23,573)	(26,240)	(22,608)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(78,000)	(44,000)	(47,588)
Maturities of short-term deposits	39,873	48,322	49,329
Purchase of property and equipment	(97)	(131)	(116)
Purchase of intangible assets	-	(185)	(181)
Net cash provided by (used in) investing activities	(38,224)	4,006	1,444
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance costs	50,407	14,359	14,089
Exercise of warrants	10,907	-	2,928
Employee stock options exercised	7	5	27
Proceeds from long-term loan, net of issuance costs	-	9,126	-
Repayments of loans	(3,376)	(2,832)	(1,543)
Repayments of lease liabilities	(196)	(220)	(445)
Net cash provided by financing activities	57,749	20,438	15,056
DECREASE IN CASH AND CASH EQUIVALENTS	(4,048)	(1,796)	(6,108)
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	16,831	12,990	10,587
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	207	(607)	(224)
CASH AND CASH EQUIVALENTS - END OF YEAR	12,990	10,587	4,255

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

	Year ended December 31,		
	2021	2022	2023
	in USD thousands		
APPENDIX			
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	703	654	1,384
Exchange differences on cash and cash equivalents	(207)	607	224
Fair value adjustments of warrants	1,936	(6,425)	11,054
Share-based compensation	1,495	2,245	2,321
Interest and exchange differences on short-term deposits	(262)	(672)	15
Interest on loans	301	1,117	1,148
Warrant issuance costs	-	171	-
Exchange differences on lease liabilities	55	(224)	(42)
Intangible assets impairment	-	-	6,703
	4,021	(2,527)	22,807
Changes in operating asset and liability items:			
Increase in trade receivables	-	-	(358)
Increase in inventory	-	-	(1,953)
Decrease (increase) in prepaid expenses and other receivables	24	(650)	(959)
Increase (decrease) in accounts payable and accruals	(564)	1,888	5,512
Increase in contract liabilities	-	-	12,957
	(540)	1,238	15,199
	3,481	(1,289)	38,006
Supplemental information on interest received in cash	138	342	2,020
Supplemental information on interest paid in cash	682	593	1,111
Supplemental information on non-cash transactions:			
Changes in right-of-use asset and lease liabilities	183	706	149
Warrant issuance costs	-	262	-
Purchase of property and equipment	-	28	-
Fair value of exercised warrants (portion related to accumulated fair value adjustments)	10,295	-	3,631

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 (primarily in clinical stages) and commercialization of therapeutics, with a focus on the fields of oncology and hematology.

The Company's American Depositary Shares ("ADSs") are traded on the NASDAQ Capital Market, and its ordinary shares are traded on the Tel Aviv Stock Exchange ("TASE"). Each ADS represents 15 ordinary shares.

The Company has two substantially wholly owned subsidiaries: (i) BioLineRx USA, Inc., incorporated in the U.S., and engaged in commercialization activities associated with the launch of motixafortide for stem-cell mobilization in the U.S.; and (ii) Agalimmune Ltd., incorporated in the United Kingdom, and engaged in clinical development activities with a focus on the field of immuno-oncology. In December 2023, the Company made a decision to terminate the development of AGI-134, the principal asset of Agalimmune Ltd., effective March 15, 2024 (see Note 9).

In September 2023, the U.S. Food and Drug Administration ("FDA") approved motixafortide in stem cell mobilization for autologous transplantation for multiple myeloma patients, and the Company has begun to independently commercialize motixafortide in the U.S.

b. Israel-Hamas war

On October 7, 2023, an unprecedented invasion was launched against Israel from the Gaza Strip by terrorists from the Hamas terrorist organization that infiltrated Israel's southern border and other areas within the country, attacking civilians and military targets while simultaneously launching extensive rocket attacks on the Israeli civilian population. These attacks resulted in extensive deaths, injuries and the kidnapping of civilians and soldiers. In response, the Security Cabinet of the State of Israel declared war against Hamas, with commencement of a military campaign against the terrorist organization, in parallel to its continued rocket and terror attacks. In addition, Hezbollah, an Islamist terrorist group that controls large portions of southern Lebanon, has attacked military and civilian targets in Northern Israel, to which Israel has responded. To date, the State of Israel continues to be at war with Hamas and in an armed conflict with Hezbollah.

The Company's headquarters and principal development operations are located in the State of Israel. In addition, most of its key employees, officers and directors are residents of Israel. The ongoing war with Hamas has not, to date, materially impacted the Company's business or operations. Furthermore, the Company does not expect any disruption to its programs or operations as a result of this situation. Nevertheless, at this time, it is not possible to predict the intensity or duration of Israel's war against Hamas, nor how this conflict will ultimately affect the Company's ongoing business and operations, nor Israel's economy in general.

NOTE 1 – GENERAL INFORMATION (cont.)

c. Going concern

The Company has incurred accumulated losses in the amount of $391 million through December 31, 2023, and it expects to continue incurring losses and negative cash flows from operations until its product or products reach commercial profitability. As mentioned in Note 3, Company management monitors rolling forecasts of the Company's liquidity reserves on the basis of anticipated cash flows and seeks to maintain liquidity balances at levels that are sufficient to meet its needs. Management believes that the Company's current cash and other resources will be sufficient to fund its projected cash requirements into 2025.

The execution of an independent commercialization plan for motixafortide in the U.S. implies an increased level of expenses prior to and following launch of the product, as well as uncertainty regarding the timing of commercial profitability. Therefore, the Company's cash flow projections are subject to various risks and uncertainties concerning their fulfilment, and these factors and the risks inherent in the Company's operations indicate that a material uncertainty exists that may cast significant doubt (or raise substantial doubt as contemplated by PCAOB standards) on the Company's ability to continue as a going concern. These consolidated financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

Management's plans include the independent commercialization of the Company's product, as aforementioned, and, if and when required, raising capital through the issuance of debt or equity securities, or capital inflows from strategic partnerships. There are no assurances, however, that the Company will be successful in obtaining the level of financing needed for its operations. If the Company is unsuccessful in commercializing its products and/or raising capital, it may need to reduce activities, or curtail or cease operations.

d. Approval of consolidated financial statements

The consolidated financial statements of the Company for the year ended December 31, 2023 were approved by the Board of Directors on March 25, 2024, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial Officer.

NOTE 2 – MATERIAL ACCOUNTING POLICIES

a. Basis of presentation

The Company's consolidated financial statements as of December 31, 2022 and 2023, and for each of the three years in the period ended December 31, 2023, have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). The material 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.

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 material 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.

NOTE 2 – MATERIAL ACCOUNTING POLICIES (cont.)

b. 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.

c. Inventory

Inventory is measured at the lower cost or net realizable value. The cost of inventories includes purchase costs, packaging and labeling costs, and other costs incurred in bringing the inventories to their present location and condition. Net realizable value is the estimated selling price of the inventories in the ordinary course of business, less the estimated costs necessary to make the sale. Pre-launch inventory is held as an asset when there is a high probability of regulatory approval for the product, see Note 1a. Before that point, a provision is made against the value to its recoverable amount; the provision is then reversed at the point when regulatory approval is received.

Inventory is written down for estimated obsolescence based upon management assumptions about future demand, expiration due date and market conditions.

d. Property and equipment

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

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

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

NOTE 2 – MATERIAL ACCOUNTING POLICIES (cont.)

e. 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 intellectual property developed by the Company to the extent that the conditions stipulated in paragraph o. below are met. Intellectual property acquired by the Company is initially measured at cost. Intellectual property used by the Company for development purposes and not yet generating revenues is not amortized and is tested annually for impairment. See g. below.

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

f. 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. See Note 9 for information about an impairment loss recorded in 2023 in connection with the decision to terminate the AGI-134 project.

g. 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 classified as a liability are also recorded as non-operating expense on the statement of comprehensive loss.

NOTE 2 – MATERIAL ACCOUNTING POLICIES (cont.)

h. 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.

With respect to long-term loans (see Note 11), a financial liability is recognized for each tranche upon drawdown. Upon initial recognition, the effective interest rate is calculated by estimating the future cash flows, including loan principal repayments, interest and royalties.

The royalty feature does not meet the definition of a derivative, is not classified separately, and is not measured separately, since it is an integral part of the loan terms and conditions and cannot be transferred or settled separately from the loan.

Determining the weighted effective interest rate requires certain judgments and estimations regarding the timing and amount of the Company's future revenues. The loans are subsequently measured at amortized cost. Furthermore, revisions to the estimated amounts or timing of future cash flows, if necessary, may result in an adjustment of the amortized cost of the loan to reflect the present value of actual and revised estimated contractual cash flows, discounted using the original effective interest rate. This adjustment will be recognized in profit or loss as financial income or expense.

Borrowings are classified as current liabilities unless the Company has an unconditional right to defer settlement of the liability for at least 12 months subsequent to the reporting period.

NOTE 2 – MATERIAL ACCOUNTING POLICIES (cont.)

i. Revenues

The Company accounts for contract 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.

Revenues from selling products

In September 2023, the FDA approved motixafortide in stem cell mobilization for autologous transplantation for multiple myeloma patients, and shortly thereafter, the Company began to independently commercialize motixafortide in the U.S.

The Company sells products mainly to wholesale distributors. Gross revenues are recognized at a point in time when control over the product is transferred to the distributors (upon delivery), at the gross selling price. The net revenues reflect gross revenues, reduced by amounts attributable to distributor fees, as well as accruals of chargebacks, rebates and returns.

The specific considerations the Company uses in estimating these amounts relating to variable consideration are as follows:

1. Distribution fees - The Company pays distribution fees to its three main distributors. The distribution fees are paid based on contractually determined rates from the gross consideration. When the service is received and the products sold to distributors, it is recognized as a reduction of revenues in the period the related revenues from the sale of products are recognized.

2. Rebates and patient discount programs - The Company offers various rebate and patient discount programs, which result in discounted prescriptions to qualified patients. The Company estimates the allowance for these rebates, based on the estimated utilization of the rebate and discount programs, at the time the revenues are recognized. These estimates are recognized as a reduction of revenues.

3. Product returns - The Company offers customers a right of return as part of the distributor agreements. The Company estimates the amount of product sales that may be returned by its customers and records this estimate as a reduction of revenues at the time of sale, based on estimates of product returns based on its own sales information, its visibility into the inventory remaining in the distribution channel, and product dating.

NOTE 2 – MATERIAL ACCOUNTING POLICIES (cont.)

i. Revenues (cont.)

Revenues from licensing agreement

According to IFRS 15, performance obligations are a promise to provide a distinct good or service or a series of distinct goods or services. Goods and services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. A good or service promised to a customer is distinct if the customer can benefit from the good or service, either on its own or together with other resources that are readily available to the customer, and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

IFRS 15 defines the 'Transaction Price' as the amount of consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services to a customer.

In accordance with IFRS 15, the Company identified a number of performance obligations (components) in the contract – in respect of which revenue will be recognized separately for each component, See Note 16.

The following assumptions were taken into account, as part of the revenue recognition process:

1) Development milestones: Variable payments, contingent on achieving additional milestones, are included in the transaction price based on the most likely amount method. Amounts included in the transaction price are recognized only when it is highly probable that a material reversal of cumulative revenues will not occur, usually upon achievement of the specific milestone, in accordance with the relevant agreement.

2) Sales-based royalties and sales-based milestones are recognized as the related sale occurs, due to the specific exception of IFRS 15 for sales-based royalties from licensing of intellectual properties.

For more information, see Note 16.

NOTE 2 – MATERIAL ACCOUNTING POLICIES (cont.)

j. Research and development expenses

Research expenses are charged to profit or loss as incurred. As of December 31, 2023, the Company has not yet capitalized development expenses.

k. 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 the 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).

Non-market performance and service conditions are included in assumptions about the number of equity instruments that are expected to vest. Performance stock unit expenses are recognized only if it is probable that the performance condition will be achieved.

l. 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 2021, 2022 and 2023, as their effect would have been anti-dilutive.

The calculation of diluted loss per share as of December 31, 2023 does not include 153,154,860 and 431,954,719 of shares underlying options, and shares underlying warrants, respectively, because the effect would be anti-dilutive.

NOTE 2 – MATERIAL ACCOUNTING POLICIES (cont.)

m. Leases

The Company's leases include property and motor vehicle leases.

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. 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.

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.

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, whichever is shorter, as follows:

	Years
Property	11
Motor vehicles	3

NOTE 2 – MATERIAL ACCOUNTING POLICIES (cont.)

n. New International Financial Reporting Standards, amendments to standards and new interpretations:

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 noncurrent, depending on the rights that exist at the end of the reporting period. Classification is unaffected by the entity's expectations 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, 2024. Earlier application is permitted. The adoption of the amendment is expected to have a material impact on the Company's financial statements as, effective January 1, 2024, the Company's warrant liabilities will be classified in current liabilities.

Deferred Tax Related to Assets and Liabilities Arising from a Single Transaction (Amendment to IAS 12)

The amendment requires companies to recognize deferred tax on transactions that, on initial recognition, give rise to equal amounts of taxable and deductible temporary differences, and will require the recognition of additional deferred tax assets and liabilities. The amendment should be applied to transactions that occur on or after the beginning of the earliest comparative period presented. In addition, entities should recognize deferred tax assets (to the extent that it is probable that they can be utilized) and deferred tax liabilities at the beginning of the earliest comparative period for all deductible and taxable temporary differences associated with right-of-use assets and lease liabilities, decommissioning, restoration and similar liabilities, and the corresponding amounts recognized as part of the cost of the related assets. The adoption of the amendment had no material impact on the Company's financial statements.

Material accounting Policies (Amendment to IAS 1)

The amendments change the requirements in IAS 1 with regard to disclosure of accounting policies. The amendments require entities to disclose their material rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general-purpose financial statements make on the basis of those financial statements.

The supporting paragraphs in IAS 1 are also amended to clarify that accounting policy information that relates to immaterial transactions, other events or conditions is immaterial and need not be disclosed. Accounting policy information may be material because of the nature of the related transactions, other events or conditions, even if the amounts are immaterial. However, not all accounting policy information relating to material transactions, other events or conditions is itself material.

These financial statements are prepared in accordance with the amendments to IAS 1 as they were effective for annual periods beginning on January 1, 2023.

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, 2023, 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 risk 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, 2023				
	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	(132)	(69)	1,457	77	162
Short term deposit	(251)	(131)	2,758	145	306
Other receivables	(31)	(16)	344	18	38
Trade payables	243	127	(2,670)	(141)	(297)
Other payables	169	89	(1,853)	(98)	(207)
Total NIS-linked balances	(2)	0	36	1	2
Euro-linked trade payables	(117)	(61)	(1,283)	67	142
Total	(119)	(61)	(1,247)	68	144

	December 31, 2022				
	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	(416)	(218)	4,573	241	508
Other receivables	(66)	(34)	721	38	80
Trade payables	38	20	(416)	(22)	(46)
Other payables	114	60	(1,257)	(66)	(140)
Total NIS-linked balances	(330)	(172)	3,621	191	402
Euro-linked trade payables	(144)	(76)	(1,590)	84	177
Total	(474)	(248)	2,031	275	579

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 information on the linkage of monetary items:

	December 31, 2022			December 31, 2023		
	Dollar	NIS	Other currencies	Dollar	NIS	Other Currencies
		USD in thousands			USD in thousands	
Assets:						
Current assets:						
Cash and cash equivalents	5,685	4,573	329	2,768	1,457	30
Short term bank deposits	40,495	-	-	35,981	2,758	-
Other receivables	-	721	-	480	350	-
	46,180	5,294	329	39,229	4,565	30
Liabilities:						
Current liabilities:						
Current maturities of long-term loans	1,542	-	-	3,145	-	-
Accounts payable and accruals:						
Trade	4,359	416	2,191	6,663	2,670	1,536
Other	487	1,257	-	1,500	1,853	-
Non-current liabilities						
Long-term loans, net of current maturities	8,626	-	-	6,628	-	-
	15,014	1,673	2,191	17,936	4,523	1,536
Net balance	31,166	3,621	(1,862)	21,293	42	(1,506)

NOTE 3 – FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk (cont.)

2) Fair value of financial instruments

As of December 31, 2023, the financial instruments of the Company consist of non-derivative assets and liabilities (primarily working capital items, deposits, and current and long-term loans), 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 non-current financial liability, see Note 12c. With regard to long-term loans, see Note 11.

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 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 trade receivables, and other receivables.

The Company's cash, cash equivalents and short-term bank deposits at December 31, 2022, and 2023 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,	
	2022	2023
	in USD thousands	
Assets:		
Cash and cash equivalents	10,587	4,255
Short-term bank deposits	40,495	38,739
Trade receivables	-	358
Other receivables	721	830
Total	51,803	44,182

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 seeks to maintain the liquidity balances at a level that is sufficient to meet its needs.

Although the Company has succeeded in generating revenues from a number of out-licensing transactions, and has recently launched commercialization of its lead program, motixafortide, in the last quarter of 2023, 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 2025. 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 and/or raise additional funding. See also Note 1c regarding the material uncertainty that may cast significant doubt about the Company's ability to continue as a going concern.

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 $11,932,000 as of December 31, 2023.

For more information on the parameters used to value the warrants, see Note 12c.

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, 2021	5,832	10,218	16,050
Changes during the year 2021:			
Principal and interest payments	(3,814)	-	(3,814)
Share premium resulting from exercise of warrants		(10,295)	(10,295)
Amounts recognized through profit and loss	739	1,936	2,675
Balance as of December 31, 2021	2,757	1,859	4,616
Changes during the year 2022:			
Net proceeds	9,126	9,075	18,201
Principal and interest payments	(3,177)	-	(3,177)
Amounts recognized through profit and loss	1,462	(6,425)	(4,963)
Balance as of December 31, 2022	10,168	4,509	14,677
Changes during the year 2023:			
Principal payments or received	(1,543)	-	(1,543)
Amounts recognized through profit and loss	1,148	11,054	12,202
Share premium resulting from exercise of warrants	-	(3,631)	(3,631)
Balance as of December 31, 2023	9,773	11,932	21,705

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, 2021, 2022 and 2023:

	Warrants in USD thousands
Balance as of January 1, 2021	10,218
Changes during 2021:	
Exercises	(10,295)
Changes in fair value through profit and loss	1,936
Balance as of December 31, 2021	1,859
Changes during 2022:	
Issuances	9,075
Changes in fair value through profit and loss	(6,425)
Balance as of December 31, 2022	4,509
Changes during 2023:	
Exercises	(3,631)
Changes in fair value through profit and loss	11,054
Balance as of December 31, 2023	11,932

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 accounting estimates are subjective and complex and consequently may differ from actual results. The estimates 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.

Below are the critical accounting estimates used in the preparation of the financial statements that required Company management to make assumptions involving significant uncertainty.

Impairment of indefinite-lived intangible assets

As mentioned in Notes 2f and 2g, the Company performs impairment reviews of intangible assets not subject to amortization on an annual basis, or more frequently if events or changes in circumstances indicate a potential impairment.

The recoverable amount is determined using discounted cash flow calculations. The analysis estimates the future cash flows the Company expects to derive from the asset, incorporates expectations about possible variations in the amount or timing of those future cash flows, as well as the uncertainty inherent in the asset, and the risk-adjusted cash flows are then discounted using the Company's estimated post-tax weighted average cost of capital ("WACC"). The main estimates used in calculating the recoverable amount include the WACC estimation and the amounts and timing of projected future cash flows. Such amounts and timing are influenced by the expected outcome of development activities, the probability of success and timing in gaining regulatory approval, size of the potential market and the Company's specific market share, either via direct sales or a potential out-licensing deal.

In light of the Company's decision to terminate AGI-134, the value of its intangible asset was written off in its entirety.

Following the approval and subsequent launch of motixafortide towards the end of 2023, the Company began to amortize the intangible asset related to motixafortide concurrently with related recognition of revenue (see Note 16).

Fair value estimations of warrants

As described in Notes 3d and 12c, 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 4 – CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS (cont.)

License revenue recognition

In determining the amounts to be recognized as revenue relating to the out-licensing transaction with HST and Gloria, the Company was required to use significant judgement in the following matters:

- The allocation of consideration between the license agreement and the SPA, based on the fair value of the Company's shares on the date considered as the closing date of the transaction
- The estimated stand-alone, selling-price value between the contract components (i.e., between the main therapeutic areas covered by the contract), as well as the performance obligations relating to each of the components
- The period of time over which revenue should be recognized for each component. The revenue recognition method is the ratio of support hours to the total hours expected to be incurred.

Recognition and measurement of allowance for rebates, chargebacks and returns

The Company makes several key estimations related to gross-to-net (GTN) revenue, which are recognized as revenue reductions and for which unsettled amounts are accrued. The primary measures calculated include rebates, Medicaid and other governmental rebates, chargebacks, and returns.

The allowance is calculated based on common practices in the industry and the estimated utilization of rebate and chargeback programs at the time revenue is recognized. The main estimates used in recognizing and measuring this allowance relate to the volume of products sold to distributors but not yet prescribed to patients. The Company periodically evaluates its estimates against actual results and updates them accordingly as necessary.

NOTE 5 – CASH AND CASH EQUIVALENTS

	December 31,	
	2022	2023
	in USD thousands	
Cash on hand and in bank	3,623	3,154
Short-term bank deposits	6,964	1,101
	10,587	4,255

The short-term bank deposits included in cash and cash equivalents bear interest at annual rates of between 0.15% and 4.55%.

NOTE 6 – SHORT-TERM BANK DEPOSITS

The short-term bank deposits are primarily in dollars and bear interest at annual rates of between 0.57% and 6.63%.

NOTE 7 – INVENTORY

	December 31,	
	2022	2023
	in USD thousands	
Raw materials	-	903
Work-in-progress	-	471
Finished goods	-	579
	-	1,953

NOTE 8 – 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	
	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,	
									2022	2023
	in USD thousands				in USD thousands				in USD thousands	
Composition in 2023										
Office furniture and equipment	244	8	-	252	138	27	-	165	106	87
Computers and communications equipment	961	101	-	1,062	712	108	-	820	249	242
Laboratory equipment	1,606	7	-	1,613	1,578	20	-	1,598	28	15
Leasehold improvements	2,036	-	-	2,036	1,693	214	-	1,907	343	129
	4,847	116	-	4,963	4,121	369	-	4,490	726	473

NOTE 9 – INTANGIBLE ASSETS

Intellectual property included the following intangible assets acquired by the Company:

- $6.7 million recorded as a result of the acquisition of Agalimmune, primarily related to its main drug candidate, AGI-134 (see Note 1a). In December 2023, the Company made a decision to terminate the development of AGI-134. Accordingly, the intellectual property related to AGI-134 has been written-off in the 2023 financial statements.

- $15.0 million associated with BL-8040 were recorded following an amendment to the in-licensing agreement with Biokine Therapeutics Ltd. ("Biokine"). This amendment reduced the payments owed by the Company on sublicense receipts (as defined in the license agreement) from 40% to 20%. This intellectual property is amortized proportionally with the revenues recognized from the licensing transaction with HST and Gloria in Asia (see Note 16), as well as in accordance with the lifespan of the patents in the U.S., following commencement of self-commercialization of motixafortide towards the end of 2023.

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	Disposal during year	Balance at end of year	Balance at beginning of year	Additions during year	Impairment during year	Balance at end of year	December 31, 2022	December 31, 2023
	in USD thousands				in USD thousands				in USD thousands	
Composition in 2023										
Intellectual property	21,792	-	450	21,342	96	-	6,703	6,799	21,696	14,543
Computer software	801	181	-	982	612	59	-	671	189	311
	22,593	181	450	22,324	708	59	6,703	7,470	21,885	14,854

NOTE 10 – 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,	
									2022	2023
	in USD thousands				in USD thousands				in USD thousands	
Composition in 2023										
Property	2,097	-	-	2,097	582	388	-	970	1,515	1,127
Motor vehicles	336	149	117	368	79	118	117	80	257	288
	2,433	149	117	2,465	661	506	117	1,050	1,772	1,415

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 2023							
Property	1,920	-	-	236	(38)	(562)	1,556
Motor vehicles	236	149	-	37	(4)	(156)	262
	2,156	149	-	273	(42)	(718)	1,818

NOTE 10 – LEASES (cont.)

C. Additional disclosures

1) The Company leases two premises – its corporate headquarters and development facilities in Modi'in, Israel, and its U.S. commercial headquarters in Waltham, Massachusetts.

   a. The Company leases its premises in Israel 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 payment is approximately $25,000. In addition, the Company pays building maintenance charges of approximately $8,000 per month.

   b. The Company leases its premises in Boston under a lease agreement entered into and commenced in October 2022. The term of the lease will expire in December 2024. The monthly lease fee is approximately $24,000.

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 approximately $303,000. To secure the terms of the lease agreements, the Company has prepaid two months of lease payments to the leasing companies.

3) As of December 31, 2023, minimum future rental payments (taking into consideration the aforementioned extension periods) under the leases are as follows:

Year	Property	Motor vehicles	Total
		in USD thousands	
2024	575	161	736
2025	292	113	405
2026	292	26	317
2027	306	-	306
2028-2030	766	-	766
	2,231	300	2,531

Extension and termination options are included in most of the property 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 lessors.

NOTE 11 – LONG-TERM LOANS

In October 2018, the Company entered into a $10 million loan agreement with Kreos Capital. This loan was repaid in full in September 2022.

In September 2022, the Company entered into a new $40 million loan agreement with Kreos Capital (via Kreos Capital VII Aggregator SCSp). Pursuant to the new agreement, the first tranche of $10 million was drawn down by the Company upon closing. The remaining $30 million will be made available in two additional tranches subject to the achievement of pre-specified milestones. The tranches are available for drawdown at the Company's discretion at various time points through October 1, 2024.

Each tranche carries a pre-defined interest-only payment period, followed by a loan principal amortization period of up to 36 months subsequent to the interest-only period. The interest-only periods are subject to possible extension based on certain pre-defined milestones. Borrowings under the financing bear interest at a fixed annual rate of 9.5% (~11.0%, including associated cash fees). As security for the loan, Kreos Capital received a first-priority secured interest in all Company assets, including intellectual property, and the Company undertook to maintain a minimum cash balance. In addition, Kreos Capital is entitled to mid-to-high single-digit royalties on motixafortide sales in the U.S., up to a pre-defined cap.

The loan's current value includes the accrual of effective interest, including estimated future royalties.

NOTE 12 – EQUITY

a. Share capital

The Company's share capital is composed of ordinary shares, as follows:

	Number of Ordinary Shares	
	December 31,	
	2022	2023
Authorized share capital	2,500,000,000	2,500,000,000
Issued and paid-up share capital	922,958,942	1,086,589,165

	In USD and NIS Amounts	
	December 31,	
	2022	2023
Authorized share capital (in NIS)	250,000,000	250,000,000
Issued and paid-up share capital (in NIS)	92,295,894	108,658,916
Issued and paid-up share capital (in USD)	27,100,201	31,355,056

NOTE 12 – 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, 2022 and 2023, all outstanding share capital consisted of ordinary shares.

c. Changes in the Company's equity

1) In connection with the loan agreement with Kreos Capital signed in October 2018 (see Note 10), 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 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 was immaterial as of December 31, 2023 (December 31, 2022 – also immaterial), and was based on the then current price of an ADS, a risk-free interest rate of 3.84%, an average standard deviation of 84.7%, and on the remaining contractual life of the warrants.

   The change in fair value for the years ended December 31, 2022 and 2023, of $36,000 and $21,000, respectively, has been recorded as non-operating income on the statement of comprehensive loss. As of December 31, 2023, 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 were exercisable immediately, were to expire five years from the date of issuance and had 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 have been classified as a 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, 2023 was immaterial (December 31, 2022 – also immaterial).

   The change in fair value for the year ended December 31, 2022 of $563,000 was recorded as non-operating income on the statement of comprehensive loss. The change in fair value for 2023 was immaterial. As of December 31, 2023, none of these warrants had been exercised, and they expired in February 2024.

NOTE 12 – 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. The Company also issued to investors in the offerings unregistered warrants to purchase 7,653,145 ADSs. The warrants were exercisable immediately, were to expire two and half years from the date of issuance and had 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 were exercisable immediately, were set to expire two and half years from the date of issuance and had 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 were classified as a 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 were charged to non-operating income and expense in the statement of comprehensive loss.

   Prior to their expiration in November 2022, 5,739,741 of these warrants were exercised.

   The change in fair value for the year ended December 31, 2022 of $1,253,000 was recorded as non-operating income 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%.

   As of December 31, 2023, none of these warrants had been exercised.

NOTE 12 – EQUITY (cont.)

c. Changes in the Company's equity (cont.)

5) In September 2022, the Company completed a registered direct offering of 13,636,365 ADSs at a price of $1.10 per ADS. The Company also issued to investors in the offering unregistered warrants to purchase 13,636,365 ADSs. The warrants are exercisable immediately, expire five years from the date of issuance and have an exercise price of $1.15 per ADS. In addition, the Company granted to the placement agent in the offering, as part of the placement fee, warrants to purchase 681,818 ADSs. These warrants are exercisable immediately, expire five years from the date of issuance and have an exercise price of $1.375 per ADS. Gross proceeds from the offering totaled $15.0 million, with net proceeds of $13.5 million, after deducting fees and expenses. The offering consideration allocated to the placement agent warrants amounted to $0.4 million.

   The warrants issued to the investors have been classified as a financial liability due to a net settlement provision. This liability was initially recognized at its fair value on the issuance date 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 is computed using the Black-Scholes option pricing model. The fair value of the warrants upon issuance was computed based on the then-current price of an ADS, a risk-free interest rate of 3.62%, and an average standard deviation of 82.5%. The gross consideration initially allocated to the investor warrants amounted to $9.1 million, with total issuance costs initially allocated to the warrants amounting to $0.8 million.

   The fair value of the warrants amounted to $11,905,000 as of December 31, 2023 (December 31, 2022 - $4,502,000), and was based on the then current price of an ADS, a risk-free interest rate of 3.9%, an average standard deviation of 86.5%, and on the remaining contractual life of the warrants.

   The changes in fair value for the years ended December 31, 2022 and 2023 of $4,573,000 and $11,033,000, respectively, have been recorded as non-operating income (expenses) in the statement of comprehensive loss.

   As of December 31, 2023, 2,545,455 of these warrants had been exercised.

   The placement agent warrants have been classified in shareholders' equity, with initial recognition at fair value on the date issued, using the same assumptions as the investor warrants.

6) On August 27, 2023, the Company entered into a securities purchase agreement, pursuant to which the Company agreed to sell in a private placement an aggregate of 6,829,137 ADSs of the Company, at a purchase price of $2.136 per ADS. Aggregate gross proceeds from the sale, which were received by the Company at closing, amounted to $14.6 million, with related issuance costs amounting to approximately $0.9 million. Pursuant to IFRS 15, approximately $12.0 million of gross proceeds and $0.7 million of issuance costs were recognized as equity. (see Note 16).

NOTE 12 – 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. During 2023, the Company issued a total of 1,501,207 ADSs under the program for total gross proceeds of approximately $2.9 million. From the effective date of the agreement through the issuance date of this report, 2,109,858 ADSs have been sold under the program for total gross proceeds of approximately $4.4 million and a total fees of approximately $0.1 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 for the grant of restricted stock units ("RSUs") and performance stock units ("PSUs"). In 2022, the Board approved certain amendments to the Plan in order to conform the Plan to U.S. tax regulations for the benefit BioLineRx USA, Inc. employees. In November 2023, the Company's Board of Directors approved to extend the term of the plan until May 2024.

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. As of December 31, 2023, 8,336,970 PSUs were vested in accordance with their original terms.

NOTE 12 – EQUITY (cont.)

e. Share-based payments (cont.)

1) Share Incentive plan – general (cont.)

As of December 31, 2023, there were 153,154,860 ordinary shares issuable upon the exercise of outstanding equity instruments under the Plan.

Company Israelis' employees and directors are granted options under Section 102 of the Israeli Income Tax Ordinance (the "Ordinance"), primarily under the "capital gains" track. Israeli non-employees of the Company (consultants and other service providers) are granted options under Section 3(i) of the Ordinance. All non-Israeli employees and non-employees of the Company are granted options as non-qualifies.

As of December 31, 2023, there were 17.7 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,					
	2021		2022		2023	
	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	35,981,579	1.5	40,956,214	0.7	89,871,858	0.4
Granted	6,588,200	0.4	53,696,305	0.3	64,855,380	0.2
Forfeited and expired	(1,438,642)	3.0	(4,618,062)	0.8	(3,804,175)	0.7
Exercised	(174,923)	0.1	(162,599)	0.1	(493,238)	0.2
Outstanding at end of year*	40,956,214	0.7	89,871,858	0.4	150,429,825	0.3
Exercisable at end of year	18,663,353	1.7	26,663,961	0.8	51,970,635	0.5

* As of December 31, 2021, 2022 and 2023, includes 4,084,748, 10,482,277, and 12,219,465 PSUs at an exercise price of 0.10 NIS (par value of ordinary shares), for which performance obligations have not been met.

NOTE 12 – EQUITY (cont.)

e. Share-based payments (cont.)

2) Employee share incentive plan (cont.):

The total consideration received from the exercise of equity instruments during 2021, 2022 and 2023 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,			
	2022		2023	
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.)
Up to 0.49	58,488,372	9.2	120,593,415	8.8
0.5-0.99	17,175,120	7.8	16,147,110	6.9
1.00-2.00	13,668,366	5.5	13,149,390	4.7
2.01-3.4	540,000	4.2	539,910	3.2
	89,871,858	8.4	150,429,825	8.2

The fair value of equity instruments granted to employees through December 31, 2023 has been determined using the Black-Scholes option-pricing model. These values are based on the following assumptions as of the applicable grant dates:

	2021	2022	2023
Expected dividend yield	0%	0%	0%
Expected volatility	67%	67%	69%
Risk-free interest rate	1%	4%	4%
Expected life of options (in years)	6	6	6

The remaining unrecognized deferred compensation expense as of December 31, 2023 was $2.7 million. This amount will be expensed over the remaining vesting period of the equity instruments.

NOTE 12 – EQUITY (cont.)

e. Share-based payments (cont.)

3) Stock options to consultants

From inception through December 31, 2021, the Company issued to consultants options for the purchase of 3,296,523 ordinary shares at a weighted average exercise price of NIS 5.23 per share.

In 2022 and 2023, the Company did not issue additional options to consultants.

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, 2023, 2,725,035 options to consultants were outstanding with a weighted average exercise price of NIS 1.01 per share and a weighted average contractual life of 6.9 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 2021, 2022 and 2023 was not material.

NOTE 13 – TAXES ON INCOME

a. Corporate taxation

The taxable income of BioLineRx Ltd., 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. The taxable income of BioLineRx USA, Inc. is subject to a federal tax rate of 21%.

b. Tax loss carryforwards

As of December 31, 2023, the tax loss carryforwards of BioLineRx Ltd. were approximately $304 million. The tax loss carryforwards have no expiration date.

c. Tax assessments

In accordance with Israeli tax regulations, the tax returns filed by BioLineRx Ltd. through the 2020 tax year are considered final.

d. Theoretical taxes

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,					
	2021		2022		2023	
		in USD thousands		in USD thousands		in USD thousands
Loss before taxes	23.0%	(27,045)	23.0%	(24,951)	23.0%	(60,614)
Theoretical tax benefit		(6,220)		(5,739)		(13,941)
Disallowed deductions (tax exempt income):						
Loss (gain) on adjustment of warrants to fair value		480		(1,478)		2,542
Share-based compensation		343		516		534
Impairment of intangible asset		-		-		1,542
Other		11		11		11
Increase in taxes for tax losses and timing differences incurred in the reporting year for which deferred taxes were not created		5,386		6,690		9,312
Taxes on income for the reported year		-		-		-

NOTE 14 – LOSS PER SHARE

The following table contains the data used in the computation of the basic loss per share:

	Year ended December 31,		
	2021	**2022**	**2023**
	in USD thousands		
Loss attributed to ordinary shares	(27,054)	(24,951)	(60,614)
	in thousands		
Number of shares used in basic calculation	662,934	773,957	963,366
	in USD		
Basic and diluted loss per ordinary share	(0.04)	(0.03)	(0.06)

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 15 – 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. Starting January 2024, the interest rate will be the 12-month SOFR rate as published on the first trading day of each calendar year. 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.

2) In connection with the in-licensing of motixafortide 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 $3.2 million as of December 31, 2023. In this regard, and in connection with the outlicensing transaction in Asia (see Note 16), as well as the commercial launch of motixafortide in the U.S., the royalty rate agreed with the IIA for motixafortide consideration received is 3.9% for sub-license consideration and 4% for direct product sales. The Company has a full right of offset for amounts payable to the IIA from all payments due to Biokine in the future.

NOTE 15 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

3) 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 15 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

3) 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 (for example, with regard to motixafortide, where the royalty rate on net sales directly commercialized by the Company payable to Biokine is 10%) 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 15 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

4) 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 December 2023, the Company determined to terminate development of AGI-134 and provided notice of its intent to terminate the Agalimmune Development Agreement, effective March 15, 2024. The Company is currently awaiting the decision of Agalimmune's founders regarding their intent to exercise their reversionary option right.

In accordance with the license agreement of motixafortide 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 $2.5 million in future milestone payments. Subject to certain limitations, if the Company independently sells products related to motixafortide, the Company will pay Biokine a royalty payment of 10% of net sales.

5) Purchase orders

The Company's outstanding open purchase order commitments as of December 31, 2023 amounted to $6.9 million.

b. Guarantees

To secure the Company's lease obligation on its Israeli 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, 2023.

NOTE 15 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

c. Contingent liabilities

On January 5, 2023, a putative securities class action complaint was filed in the U.S. against the Company and its Chief Executive Officer. The complaint claims that the Company made false and materially misleading statements and failed to disclose material adverse facts pertaining to its financial position with regard to the development of motixafortide and that the Company would require a loan and a securities offering to commercialize motixafortide. The complaint asserts a putative class period of February 23, 2021 to September 19, 2022, inclusive, and seeks certification as a class action and an unspecified amount of damages. On July 5, 2023, an amended complaint was filed, alleging the same claims and adding the Company's Chief Financial Officer. On September 5, 2023, the Company, its Chief Executive Officer and its Chief Financial Officer filed a motion to dismiss the amended complaint in its entirety. The motion has been fully briefed and is sub judice. The Company also received, on February 5, 2023, a substantially similar lawsuit and motion to approve the lawsuit as a class action in the Tel Aviv District Court. The total amount claimed in Tel Aviv, if the lawsuit is certified as a class action, is approximately NIS 113.5 million (approximately $32 million).

The outcome of both legal proceedings is uncertain at this point. Based on an initial evaluation, management of the Company believes they are without merit and intends to vigorously defend against such actions.

NOTE 16 – LICENSE AND SECURITIES PURCHASE AGREEMENTS

On August 27, 2023, the Company entered into a license agreement (the "License Agreement") with Hong Seng Technology Limited ("HST") and Guangzhou Gloria Biosciences Co., Ltd. ("Gloria" and together with HST, the "Purchaser Parties" or the "Licensee"), pursuant to which the Company granted HST an exclusive, royalty-bearing, sublicensable license to develop and commercialize motixafortide in Asia (other than Israel and certain other countries) (collectively, the "Territory") and to engage and authorize Gloria to perform services under the License Agreement in the Territory. In addition, the Company granted the Licensee a first offer right with respect to the grant of certain rights in motixafortide outside of the Territory. The License Agreement became effective on October 12, 2023, following fulfillment of all closing conditions.

Pursuant to the terms of the License Agreement, the Licensee paid an upfront payment of $15 million, which was received by the Company at closing. The Company is also entitled to up to $49 million based on the achievement of certain development and regulatory milestones in China and Japan, and up to $197 million in sales milestones based on defined sales targets of motixafortide in the Territory. In addition, the Company is eligible to receive tiered double-digit royalties (ranging from 10-20%), on a country-by-country basis, on aggregate net sales of motixafortide in the Territory during the initial royalty term of at least 15 years, with a reduction of the royalties payable following the end of the initial royalty term, as well as upon the occurrence of certain events.

In connection with the License Agreement, on August 27, 2023, the Company also entered into a securities purchase agreement (the "Purchase Agreement") with HST and Gloria, pursuant to which the Company agreed to sell in a private placement an aggregate of 6,829,137 ADSs of the Company, at a purchase price of $2.136 per ADS. Aggregate gross proceeds from the sale, which were received by the Company at closing, amounted to $14.6 million, with related issuance costs amounting to approximately $0.9 million. No warrants were issued in the transaction.

In accordance with IFRS 15, both agreements have been treated as a single unit of account, with the consideration combined and subsequently allocated between the Purchase Agreement and the License Agreement.

- TheOf the total consideration received wasamounting to $29.6 million; approximately, $12.0 million were allocated to the Purchase Agreement, and $1417.6 million were allocated to the share purchase agreement, and license agreement respectively.License Agreement
- Costs in the amount of $0.7 million directly attributable to the share purchase agreementPurchase Agreement were recognized as a deduction fromreduction in equity in the amount of $0.704 million.

The Company has identified the following performance obligations in the contract, each to be recognized separately:

1. SCM license
2. SCM support services
3. PDAC license and related support services

With regard to PDAC, the Company determined that the license, together with the associated support services, should be combined into a single performance obligation, since the Licensee cannot benefit from the license without the associated support services. The support services are highly specialized for the licensed product in this indication.

Licensing rights for other indications and related support were deemed immaterial.

NOTE 16 – LICENSE AND SECURITIES PURCHASE AGREEMENTS (cont.)

The fixed transaction price has been allocated among the performance obligations based on similar price offers received by the Company, with the assistance of a valuation specialist. The variable consideration related to the performance obligations was not taken into account in the fixed transaction price due to uncertainty.

The variable consideration related to certain performance obligations was not taken into account in the fixed transaction price due to uncertainty.

Revenue will be recognized in the Company's financial statements as follows:

a. Revenue for the SCM license was recognized in Q4 2023, upon the transfer of control over the license to the licensee, in the amount of approximately $2.0 million.

b. Revenue from providing the SCM support services will be recognized using the input method, which is based on costs incurred and labor hours expended, expected to result in straight-line revenue recognition over six months, totaling approximately $0.1 million.

c. Revenue from the PDAC performance obligation will be recognized over time, with the percentage of completion determined based on support hours incurred, and expected to be recognized over twelve monthsthrough the end of 2024, in the total amount of $15.5 million.

Costs associated directly with the license agreement have been allocated to the performance obligation above and recognized concurrently with the revenue recognition.

NOTE 17 – TRANSACTIONS AND BALANCES WITH RELATED PARTIES

Transactions with related parties

Expenses:

	Year ended December 31,		
	2021	2022	2023
	in USD thousands		
Benefits to related parties:			
Compensation and benefits to senior management, including benefit component of equity instrument grants	2,302	2,968	3,155
Compensation and benefits to directors, including benefit component of equity instrument grants	300	507	587

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,		
	2021	2022	2023
	in USD thousands		
Salaries and other short-term employee benefits	1,883	2,298	2,425
Post-employment benefits	136	131	256
Other long-term benefits	35	35	31
Share-based compensation	548	1,011	1,030
	2,602	3,475	3,742

NOTE 18 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

a. Other receivables

	December 31,	
	2022	2023
	in USD thousands	
Advance payments	-	480
Government institutions	687	245
Other	34	105
	721	830

b. Accounts payable and accruals

	December 31,	
	2022	2023
	in USD thousands	
1) Trade:		
Accounts payable:		
Overseas	6,061	7,704
In Israel	905	3,165
	6,966	10,869
2) Other:		
Payroll and related expenses	931	2,184
Accrued expenses	352	662
Accrual for vacation and recreation pay	377	419
Other	84	88
	1,744	3,353

The carrying amounts of accounts payable and accruals approximate their fair value, as the effect of discounting is not material.

c. Revenues

	Year ended December 31,		
	2021	2022	2023
		in USD thousands	
License revenues (see Note 16)	-	-	4,610
Product sales, net	-	-	190
	-	-	4,800

NOTE 18 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

d. Cost of revenues

	Year ended December 31,		
	2021	**2022**	**2023**
	in USD thousands		
Cost related to license revenues	-	-	3,230
Amortization of intangible asset in respect of license revenues	-	-	450
Cost of product sales	-	-	12
	-	-	3,692

e. Research and development expenses

	Year ended December 31,		
	2021	**2022**	**2023**
	in USD thousands		
Research and development services	12,088	9,296	4,603
Payroll and related expenses	4,074	4,495	4,452
Lab, occupancy and telephone	882	902	969
Professional fees	595	954	935
Share-based compensation	971	1,198	760
Depreciation and amortization	660	615	583
Other	196	169	217
	19,466	17,629	12,519

f. Sales and marketing expenses

	Year ended December 31,		
	2021	**2022**	**2023**
	in USD thousands		
Payroll and related expenses	308	947	8,868
Medical Affairs	-	1,316	4,824
Marketing	700	1,805	4,091
Office related expenses	-	519	1,923
Market Access	-	1,023	1,606
Business Analytics	-	106	1,005
Travel	25	84	986
Share-based compensation	(59)	112	751
Professional fees	-	521	745
Depreciation and amortization	-	-	314
Other	29	29	158
	1,003	6,462	25,270

NOTE 18 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

g. General and administrative expenses

	Year ended December 31,		
	2021	**2022**	**2023**
	in USD thousands		
Payroll and related expenses	1,408	1,706	2,117
Professional fees	1,103	1,248	2,028
Insurance	1,064	1,046	939
Share-based compensation	583	895	780
Depreciation	42	39	37
Other	108	132	409
	4,308	5,066	6,310

h. Non-operating income (expenses), net

	Year ended December 31,		
	2021	**2022**	**2023**
	in USD thousands		
Changes in fair value of warrants	(1,936)	6,425	(11,054)
Issuance costs	-	(762)	-
Other	106	7	235
	(1,830)	5,670	(10,819)

i. Financial income

	Year ended December 31,		
	2021	**2022**	**2023**
	in USD thousands		
Interest income	277	694	2,007
Exchange differences, net	282	-	61
	559	694	2,068

j. Financial expenses

	Year ended December 31,		
	2021	**2022**	**2023**
	in USD thousands		
Interest expense	984	1,786	2,144
Bank commissions	22	26	25
Exchange differences, net	-	346	-
	1,006	2,158	2,169

Exhibit 2.2

DESCRIPTION OF SECURITIES
REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT

As of December 31, 2023, BioLineRx Ltd. had two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended, or Exchange Act: our ordinary shares and our American Depositary Shares, or ADSs. References herein to "we," "us," "our" and the "Company" refer to BioLineRx Ltd. and its subsidiary.

General

We were incorporated under the laws of the State of Israel in 2003 under the name "BioLineRx Ltd.". Our registration number with the Israeli Registrar of Companies is 513398750. Our purpose is set forth in Section 2 of our Articles of Association and includes every lawful purpose.

Listing

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.

Ordinary Shares

Our authorized share capital consists of 2,500,000,000 ordinary shares, par value NIS 0.1 per share.

Transfer of Shares

Our ordinary shares that are fully paid for are issued in registered form and may be freely transferred under our Articles of Association, unless the transfer is restricted or prohibited by another instrument, applicable law or the rules of a stock exchange on which the shares are traded. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our Articles of Association or the laws of the State of Israel, except under certain circumstances with respect to subjects of some countries which are, or have been, in a state of war with Israel.

Changes in Capital

Our Articles of Association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Israeli Companies Law, 1999, or the Companies Law, and must be approved by a resolution duly passed by our shareholders at a general or extraordinary meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings and profits, require a resolution of our Board of Directors and court approval.

Dividends and Liquidation Rights

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the company's articles of association provide otherwise. Our Articles of Association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our board of directors.

Pursuant to the Companies Law, we may only distribute dividends out of the higher of (a) retained earnings and (b) earnings generated over the two most recent fiscal years years, as such terms are defined in the Companies Law, according to our then last reviewed or audited financial reports, provided that the date of the financial reports is not more than six months prior to the date of distribution (referred to as the "profit test"), provided that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due (referred to as the "solvency test"). Notwithstanding the foregoing, in the event that a company does meet the profit test, dividends may be paid with the approval of a court, provided that the court is convinced that the company meets the solvency test. However, in accordance with the (Relief for Companies the Shares of which are Registered for Trading Outside of Israel) – 2000, or the Relief Regulations, as a company whose shares are listed on a foreign exchange referenced in the second or third addendum to the Israeli Securities Law (which include, among others, the NASDAQ Capital Market), our board of directors may resolve to distribute a dividend by way of a share repurchase program if the company does not meet the profit test without seeking the approval of the court, subject to the following: (i) the company meets the solvency test; and (ii) we provided a notice to certain creditors regarding our intention to distribute a dividend by way of a share repurchase program in accordance with the notice requirements set forth in the Relief Regulations and no such creditor submits an objection within 30 days of the notice (otherwise, court approval would be required for such distribution in accordance with the requirements of the Companies Law).

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential dividend or distribution rights that may be authorized in the future.

Election of Directors

Under our Articles of Association, our board of directors must consist of at least five and not more than 10 directors (including external directors under Israeli law, if any). Our ordinary shares do not have cumulative voting rights in the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting and voting on the matter have the power to elect all of our directors (other than with respect to the special approval requirements for the election of external directors, if applicable).

Pursuant to our Articles of Association, other than the external directors (if any), for whom special election requirements apply under the Companies Law, our directors are divided into three classes, one class being elected each year at the annual general meeting of our shareholders, and serve on our board of directors until the third annual general meeting following such election or re-election or until they are removed by a vote of 65% of the total voting power 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 (who are not external directors) to fill vacancies on the board of directors up to the maximum number of directors permitted under our Articles of Association. Any director so appointed serves for a term of office equal to the remaining period of the term of office of the director whose office has been vacated (or in the case of any new director, for a term of office according to the class to which such director was assigned upon appointment).

Quorum

The quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or written ballot who hold or represent between them at least 25% of the total outstanding voting rights.

A meeting adjourned for lack of a quorum is adjourned to the same day in the following week at the same time and place or on a later date if so specified in the summons or notice of the meeting. At the reconvened meeting, any number of our shareholders present in person or by proxy shall constitute a lawful quorum.

Vote Requirements

Holders of ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders.

Our Articles of Association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by applicable law or by our Articles of Association. Under the Companies Law, certain actions require a special majority, including: (i) the approval of an extraordinary transaction with a controlling shareholder or in which the controlling shareholder has a personal interest, (ii) the terms of employment or other engagement of a controlling shareholder of the company or a controlling shareholder's relative (even if such terms are not extraordinary) and (iii) approval of certain compensation-related matters, such as approval of a compensation policy, approval of executive officer compensation inconsistent with our compensation policy or the compensation of our chief executive officer (subject to limited exceptions). Under our Articles of Association, the alteration of the rights, privileges, preferences or obligations of any class of our shares (to the extent there are classes other than ordinary shares) may require a simple majority of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting. Our Articles of Association also provide that the removal of any director from office or the amendment of such provision, or certain other provisions regarding our staggered board require the vote of at least 65% of the total voting power of our shareholders. Another exception to the simple majority vote requirement is a resolution for the voluntary winding up, or an approval of a scheme of arrangement or reorganization, of the company pursuant to Section 350 of the Companies Law, which requires the approval of a majority of the holders holding at least 75% of the voting rights represented at the meeting and voting on the resolution.

Access to Corporate Records

Under the Companies Law, all shareholders of a company generally have the right to review minutes of the company's general meetings, its shareholders register and principal shareholders register, articles of association, financial statements and any document it is required by law to file publicly with the Israeli Companies Registrar and the Israel Securities Authority. Furthermore, any of our shareholders may request access to review any document in our possession that relates to any action or transaction with a related party, interested party or office holder that requires shareholder approval under the Companies Law. However, we may deny such a request to review a document if we determine that the request was not made in good faith, that the document contains a trade secret or a patent or that the document's disclosure may otherwise prejudice our interests.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the target company's voting rights or issued and outstanding share capital (or a class thereof), is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company (or the applicable class). If (a) the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company (or of the applicable class) and the shareholders who accept the offer constitute a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (b) the shareholders who did not accept the tender offer hold less than 2% of the issued and outstanding share capital of the company (or of the applicable class), all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law.

However, a shareholder that had its shares so transferred may petition the court within six months from the date of acceptance of the full tender offer, regardless of whether such shareholder agreed to the tender, to determine whether the tender offer was for less than fair value and whether the fair value should be paid as determined by the court unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights. If the full tender offer was not accepted in accordance with any of the above alternatives, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital (or of the applicable class) from shareholders who accepted the tender offer. Shares purchased in contradiction to the special tender offer rules under the Companies Law will have no rights and will become dormant shares.

Special Tender Offer

The Companies Law provides that an acquisition of shares of a public Israeli company must be made by means of a special tender offer if as a result of the acquisition, the purchaser would become a holder of 25% or more of the voting rights in the company, unless one of the exemptions in the Companies Law is met. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a tender offer if as a result of the acquisition the purchaser would become a holder of 45% or more of the voting rights in the company, if there is no other shareholder of the company who holds 45% or more of the voting rights in the company. These requirements do not apply if the acquisition (i) occurs in the context of a private placement that received shareholder approval as a private placement whose purpose is to give the acquirer at least 25% of the voting rights in the company if there is no person who holds at least 25% of the voting rights in the company, or as a private offering whose purpose is to give the acquirer 45% of the voting rights in the company, if there is no person who holds 45% of the voting rights in the company; (ii) was from a shareholder holding at least 25% of the voting rights in the company and resulted in the acquirer becoming a holder of at least 25% of the voting rights in the company; or (iii) was from a holder of more than 45% of the voting rights in the company and resulted in the acquirer becoming a holder of more than 45% of the voting rights in the company.

A special tender offer must be extended to all shareholders of a company. A special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer.

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer or shall abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention. The board of directors shall also disclose any personal interest that any of the directors has with respect to the special tender offer or in connection therewith. An office holder in a target company who, in his or her capacity as an office holder, performs an action the purpose of which is to cause the failure of an existing or foreseeable special tender offer or to impair the chances of its acceptance, is liable to the potential purchaser and shareholders for damages resulting from his acts, unless such office holder acted in good faith and had reasonable grounds to believe he or she was acting for the benefit of the company. However, office holders of the target company may negotiate with the potential purchaser in order to improve the terms of the special tender offer, and may further negotiate with third parties in order to obtain a competing offer.

If a special tender offer was accepted by a majority of the shareholders who announced their stand on such offer, then shareholders who did not respond to the special tender offer or objected to the special tender offer may accept the offer within four days of the last day set for the acceptance of the offer and they will be considered to have accepted the offer from the first day it was made.

If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer. Shares purchased in contradiction to the special tender offer rules under the Companies Law will have no rights and will become dormant shares.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, a majority of each party's shares voted on the proposed merger at a shareholders' meeting called with at least 35 days' prior notice. The board of directors of a merging company is required pursuant to the Companies Law to discuss and determine whether in its opinion there exists a reasonable concern that as a result of a proposed merger, the surviving company will not be able to satisfy its obligations towards its creditors, taking into account the financial condition of the merging companies. If the board of directors determines that such a concern exists, it may not approve a proposed merger. Following the approval of the board of directors of each of the merging companies, the boards of directors must jointly prepare a merger proposal for submission to the Israeli Registrar of Companies.

For purposes of the shareholder vote of a merging company whose shares are held by the other merging company, or by a person or entity holding 25% or more of the voting rights at the general meeting of shareholders of the other merging company, or by a person or entity holding the right to appoint 25% or more of the directors of the other merging company (referred to as "Affiliated Parties"), unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares represented at the shareholders meeting that are held by parties other than Affiliated Parties or any one on their behalf including their relatives or corporations controlled by any of them, vote against the merger. In addition, if the non-surviving entity of the merger has more than one class of shares, the merger must be approved by each class of shareholders.

If the transaction would have been approved but for the separate approval of each class of shares or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the valuation of the merging companies and the consideration offered to the shareholders. If a merger is with a company's controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders.

Under the Companies Law and the regulations promulgated thereunder, each merging company must deliver a copy of the proposed merger proposal to its secured creditors and inform unsecured creditors of the merger proposal and its content. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of any of the parties to the merger, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and 30 days have passed from the date the merger was approved by the shareholders of each party.

Antitakeover Measures

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. As of the date hereof, we do not have any authorized or issued shares other than our ordinary shares. In the future, if we do create and issue a class of shares other than ordinary shares, such class of shares, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization of a new class of shares will require an amendment to our Articles of Association which requires the prior approval of the holders of a majority of our shares at a general meeting. Shareholders voting in such meeting will be subject to the restrictions provided in the Companies Law as described above. In addition, the Israeli Securities Law and the rules and regulations of the Tel Aviv Stock Exchange, or the TASE, also limit the terms permitted with respect to a new class of shares created by a public company whose shares are traded on the TASE and prohibit any such new class of shares from having voting rights. In addition, as disclosed above under "—Election of Directors" we have a classified board structure, which will effectively limit the ability of any investor or potential investor or group of investors or potential investors to gain control of our board of directors.

Debt Securities

We do not have any debt securities that are registered under Section 12 of the Securities Exchange Act of 1934, or the Securities Act.

Warrants and Rights

We do not have any warrants or rights that are registered under Section 12 of the Securities Act.

Other Securities

We do not have any other securities that are registered under Section 12 of the Securities Act.

American Depositary Shares

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 our most recent 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.

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 26, 2024

/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 26, 2024

/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, 2023 (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 26, 2024

/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, 2023 (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 26, 2024

/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, 333-208865, 333-269334 and 333-276325) and Form F-3 (No. 333,239485, 333-229021 and 333-276323) of BioLineRx Ltd. of our report dated March 26, 2024 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 26, 2024

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

Exhibit 97.1

BioLineRx Ltd.
Executive Officer Clawback Policy

Approved by the Compensation Committee of the Board of Directors on November___, 2023 (the "Adoption Date")

I. Purpose

This Executive Officer "Clawback" Policy (or "Policy") describes the circumstances under which Covered Persons, as defined herein, of BioLineRx Ltd. and any of its direct or indirect subsidiaries (the "Company") will be required to repay or return Erroneously-Awarded Compensation, as defined herein, to the Company.

This Policy and any terms used in this Policy shall be construed in accordance with any SEC regulations promulgated to comply with Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, including without limitation Rule 10D-1 promulgated under the Securities Exchange Act of 1934, as amended, and the rules adopted by Nasdaq, as well as the provisions of the Israeli Companies Law of 1999 (the "Companies Law").

Each Covered Person of the Company shall sign an Acknowledgement and Agreement to the Clawback Policy in the form attached hereto as Exhibit A as a condition to his or her participation in any of the Company's incentive-based compensation programs; provided that this Policy shall apply to each Covered Person irrespective of whether such Covered Person shall have failed, for any reason, to have executed such Acknowledgement and Agreement.

II. Definitions

For purposes of this Policy, the following capitalized terms shall have the respective meanings set forth below:

(a) "**Accounting Restatement**" shall mean an accounting restatement (i) due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial restatements that is material to the previously issued financial statements (a "Big R" restatement), or (ii) that corrects an error that is not material to previously issued financial statements, but would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "little r" restatement). Notwithstanding the foregoing, none of the following changes to the Company's financial statements represent error corrections and shall not be deemed an Accounting Restatement: (a) retrospective application of a change in accounting principle; (b) retrospective revision to reportable segment information due to a change in the structure of the Company's internal organization; (c) retrospective reclassification due to a discontinued operation; (d) retrospective application of a change in reporting entity, such as from a reorganization of entities under common control; and (e) retrospective revision for share splits, reverse share splits, share dividends or other changes in capital structure.

(b) "**Board**" shall mean the Board of Directors of the Company.

(c) "**Clawback-Eligible Incentive Compensation**" shall mean, in connection with an Accounting Restatement, any Incentive-Based Compensation Received by a Covered Person (regardless of whether such Covered Person was serving at the time that Erroneously-Awarded Compensation is required to be repaid) (i) on or after the Nasdaq Effective Date, (ii) after beginning service as a Covered Person, (iii) while the Company has a class of securities listed on a national securities exchange or national securities association and (iv) during the Clawback Period.

(d) "**Clawback Period**" shall mean, with respect to any Accounting Restatement, the three completed fiscal years immediately preceding the Restatement Date and any transition period (that results from a change in the Company's fiscal year) of less than nine months within or immediately following those three completed fiscal years.

(e) "**Committee**" shall mean the Compensation Committee of the Board.

(f) "**Covered Person**" shall mean any person who is, or was at any time, during the Clawback Period, an Executive Officer of the Company. For the avoidance of doubt, Covered Person may include a former Executive Officer that left the Company, retired, or transitioned to an employee non-Executive Officer role (including after serving as an Executive Officer in an interim capacity) during the Clawback Period, and this Policy applies regardless of whether the Covered Person was at fault for an accounting error or other action that resulted in, or contributed to, the Accounting Restatement.

(g) "**Erroneously-Awarded Compensation**" shall mean the amount of Clawback-Eligible Incentive Compensation that exceeds the amount of Incentive-Based Compensation that otherwise would have been Received had it been determined based on the restated amounts. This amount must be computed without regard to any taxes paid.

(h) "**Executive Officer**" shall mean (i) the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, (ii) any other person (including an officer of the Company's parent(s) or subsidiaries) who performs similar policy-making functions for the Company, or (iii) an "Officer" within the meaning set forth in the Companies Law. For the sake of clarity, at a minimum, all persons who would be executive officers pursuant to Rule 401(b) under Regulation S-K shall be deemed "Executive Officers."

(i) "**Financial Reporting Measures**" shall mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and all other measures that are derived wholly or in part from such measures, including, without limitation, measures that are "non-GAAP financial measures" for purposes of Exchange Act Regulation G and Item 10(e) of Regulation S-K, as well other measures, metrics and ratios that are not non- GAAP measures. For purposes of this Policy, Financial Reporting Measures shall include stock price and total shareholder return (and any measures that are derived wholly or in part from stock price or total shareholder return). A Financial Reporting Measure need not be presented within the Company's financial statements or included in a Company filing with the SEC.

(j) "**Incentive-Based Compensation**" shall have the meaning set forth in Section III below.

(k) "**Nasdaq**" shall mean The Nasdaq Stock Market.

(l) "**Nasdaq Effective Date**" shall mean October 2, 2023.

(m) "**Policy**" shall mean this Executive Officer Clawback Policy, as the same may be amended and/or restated from time to time.

(n) "**Received**" shall mean Incentive-Based Compensation received, or deemed to be received, in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation is attained, even if the payment or grant occurs after the fiscal period.

(o) "**Repayment Agreement**" shall have the meaning set forth in Section V below.

(p) "**Restatement Date**" shall mean the earlier of (i) the date the Board, a committee of the Board or the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (ii) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

(q) "**SARs**" shall mean stock appreciation rights.

(r) "**SEC**" shall mean the U.S. Securities and Exchange Commission.

III. Incentive-Based Compensation

"Incentive-Based Compensation" shall mean any compensation that is granted, earned, or vested wholly or in part upon the attainment of a Financial Reporting Measure.

For purposes of this Policy, specific examples of Incentive-Based Compensation include, but are not limited to:

- Non-equity incentive plan awards that are earned based, wholly or in part, based on satisfaction of a Financial Reporting Measure performance goal;
- Bonuses paid from a "bonus pool," the size of which is determined, wholly or in part, based on satisfaction of a Financial Reporting Measure performance goal;
- Other cash awards based on satisfaction of a Financial Reporting Measure performance goal;
- Restricted stock, restricted stock units, performance share units, stock options and SARs that are granted or become vested, wholly or in part, on satisfaction of a Financial Reporting Measure performance goal; and
- Proceeds received upon the sale of shares acquired through an incentive plan that were granted or vested based, wholly or in part, on satisfaction of a Financial Reporting Measure performance goal.

For purposes of this Policy, Incentive-Based Compensation excludes:

- Any base salaries (except with respect to any salary increases earned, wholly or in part, based on satisfaction of a Financial Reporting Measure performance goal);
- Bonuses paid solely at the discretion of the Committee or Board that are not paid from a "bonus pool" that is determined by satisfying a Financial Reporting Measure performance goal;
- Bonuses paid solely upon satisfying one or more subjective standards and/or completion of a specified employment period;
- Non-equity incentive plan awards earned solely upon satisfying one or more strategic measures or operational measures; and
- Equity awards that vest solely based on the passage of time and/or satisfaction of one or more non-Financial Reporting Measures.

IV. Determination and Calculation of Erroneously-Awarded Compensation

In the event of an Accounting Restatement, the Committee shall promptly determine the amount of any Erroneously-Awarded Compensation for each Executive Officer in connection with such Accounting Restatement and shall promptly thereafter provide each Executive Officer with a written notice containing the amount of Erroneously-Awarded Compensation and a demand for repayment, forfeiture or return thereof, as applicable.

(a) **Cash Awards**. With respect to cash awards, the Erroneously-Awarded Compensation is the difference between the amount of the cash award (whether payable as a lump sum or over time) that was Received and the amount that should have been Received applying the restated Financial Reporting Measure.

(b) **Cash Awards Paid From Bonus Pools**. With respect to cash awards paid from bonus pools, the Erroneously-Awarded Compensation is the pro rata portion of any deficiency that results from the aggregate bonus pool that is reduced based on applying the restated Financial Reporting Measure.

(c) **Equity Awards**. With respect to equity awards, if the shares, options, SARs or other equity awards are still held at the time of recovery, the Erroneously-Awarded Compensation is the number of such securities Received in excess of the number that should have been received applying the restated Financial Reporting Measure (or the value in excess of that number). If the options, SARs or other equity awards have been exercised, vested, settled or otherwise converted into underlying shares, but the underlying shares have not been sold, the Erroneously-Awarded Compensation is the number of shares underlying the excess options or SARs (or the value thereof). If the underlying shares have already been sold, the Erroneously-Awarded Compensation is the higher of the value of the stock upon vesting, exercise or sale.

(d) **Compensation Based on Stock Price or Total Shareholder Return**. For Incentive-Based Compensation based on (or derived from) stock price or total shareholder return, where the amount of Erroneously-Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement, the amount shall be determined by the Committee based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received (in which case, the Committee shall maintain documentation of such determination of that reasonable estimate and provide such documentation to Nasdaq in accordance with applicable listing standards).

V. Recovery of Erroneously-Awarded Compensation

Once the Committee has determined the amount of Erroneously-Awarded Compensation recoverable from the applicable Covered Person, the Committee shall take all necessary actions to recover the Erroneously-Awarded Compensation. Unless otherwise determined by the Committee, the Committee shall pursue the recovery of Erroneously-Awarded Compensation in accordance with the below:

(a) **Cash Awards**. With respect to cash awards, the Committee shall either (i) require the Covered Person to repay the Erroneously-Awarded Compensation in a lump sum in cash (or such property as the Committee agrees to accept with a value equal to such Erroneously-Awarded Compensation) reasonably promptly following the Restatement Date or (ii) if approved by the Committee, offer to enter into a Repayment Agreement. If the Covered Person accepts such offer and signs the Repayment Agreement within a reasonable time as determined by the Committee, the Company shall countersign such Repayment Agreement.

(b) **Unvested Equity Awards**. With respect to those equity awards that have not yet vested, the Committee shall take all necessary action to cancel, or otherwise cause to be forfeited, the awards in the amount of the Erroneously-Awarded Compensation.

(c) **Vested Equity Awards**. With respect to those equity awards that have vested and the underlying shares have not been sold, the Committee shall take all necessary action to cause the Covered Person to deliver and surrender the underlying shares in the amount of the Erroneously-Awarded Compensation.

In the event that the Covered Person has sold the underlying shares, the Committee shall either (i) require the Covered Person to repay the Erroneously-Awarded Compensation in a lump sum in cash (or such property as the Committee agrees to accept with a value equal to such Erroneously-Awarded Compensation) reasonably promptly following the Restatement Date or (ii) if approved by the Committee, offer to enter into a Repayment Agreement. If the Covered Person accepts such offer and signs the Repayment Agreement within a reasonable time as determined by the Committee, the Company shall countersign such Repayment Agreement.

(d) **Repayment Agreement**. "Repayment Agreement" shall mean an agreement (in a form reasonably acceptable to the Committee) with the Covered Person for the repayment of the Erroneously-Awarded Compensation as promptly as possible without unreasonable economic hardship to the Covered Person.

(e) **Effect of Non-Repayment**. To the extent that a Covered Person fails to repay all Erroneously-Awarded Compensation to the Company when due (as determined in accordance with this Policy), the Company shall, or shall cause one or more other members of the Company to, take all actions reasonable and appropriate to recover such Erroneously-Awarded Compensation from the applicable Covered Person. Unless otherwise determined by the Committee in its discretion, the applicable Covered Person shall be required to reimburse the Company for all expenses reasonably incurred (including legal fees) by the Company in recovering such Erroneously-Awarded Compensation in accordance with the immediately preceding sentence.

The Committee shall have broad discretion to determine the appropriate means of recovery of Erroneously-Awarded Compensation based on all applicable facts and circumstances and taking into account the time value of money and the cost to shareholders of delaying recovery. However, in no event may the Company accept an amount that is less than the amount of Erroneously-Awarded Compensation in satisfaction of a Covered Person's obligations hereunder.

VI. Discretionary Recovery

Notwithstanding anything herein to the contrary, the Company shall not be required to take action to recover Erroneously-Awarded Compensation if any one of the following conditions are met and the Committee determines that recovery would be impracticable:

(i) The direct expenses paid to a third party to assist in enforcing this Policy against a Covered Person would exceed the amount to be recovered, after the Company has made a reasonable attempt to recover the applicable Erroneously-Awarded Compensation, documented such attempts and provided such documentation to Nasdaq;

(ii) Recovery would violate home country law where that law was adopted prior to November 28, 2022, provided that, before determining that it would be impracticable to recover any amount of Erroneously-Awarded Compensation based on violation of home country law, the Company has obtained an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such a violation and a copy of the opinion is provided to Nasdaq; or

(iii) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

VII. Reporting and Disclosure Requirements

The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the federal securities laws, including the disclosure required by the applicable filings required to be made with the SEC.

VIII. Effective Date

This Policy shall apply to any Incentive-Based Compensation Received on or after the Nasdaq Effective Date.

IX. No Indemnification

The Company shall not indemnify any Covered Person against the loss of Erroneously-Awarded Compensation and shall not pay, or reimburse any Covered Persons for premiums, for any insurance policy to fund such Covered Person's potential recovery obligations.

X. Administration

The Committee has the sole discretion to administer this Policy and ensure compliance with Nasdaq Rules and any other applicable law, regulation, rule or interpretation of the SEC or Nasdaq promulgated or issued in connection therewith. Actions of the Committee pursuant to this Policy shall be taken by the vote of a majority of its members. The Committee shall, subject to the provisions of this Policy, make such determinations and interpretations and take such actions as it deems necessary, appropriate, or advisable. All determinations and interpretations made by the Committee shall be final, binding, and conclusive.

XI. Amendment; Termination

The Committee may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary, including as and when it determines that it is legally required by any federal securities laws, SEC rule, the Companies Law or the rules of any national securities exchange or national securities association on which the Company's securities are then listed. The Committee may terminate this Policy at any time. Notwithstanding anything in this Section XI to the contrary, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by the Company contemporaneously with such amendment or termination) cause the Company to violate any federal securities laws, SEC rule, the Companies Law or the rules of any national securities exchange or national securities association on which the Company's securities are then listed.

XII. Other Recoupment Rights; No Additional Payments

The Committee intends that this Policy will be applied to the fullest extent of the law. The Committee may require that any employment agreement, equity award agreement or any other agreement entered into on or after the Adoption Date shall, as a condition to the grant of any benefit thereunder, require a Covered Person to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, and shall not derogate from, any other rights or obligations under applicable law, regulation, or rule or pursuant to any similar policy in any employment agreement, equity plan, compensation policy, equity award agreement or similar arrangement and any other legal remedies available to the Company. However, this Policy shall not provide for recovery of Incentive-Based Compensation that the Company has already recovered pursuant to Section 304 of the Sarbanes-Oxley Act or other recovery obligations.

XIII. Successors

This Policy shall be binding and enforceable against all Covered Persons and their beneficiaries, heirs, executors, administrators, or other legal representatives.

Exhibit A

ACKNOWLEDGEMENT AND AGREEMENT
TO THE
EXECUTIVE OFFICER CLAWBACK POLICY
OF
BIOLINERX LTD.

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of BioLineRx Ltd. Executive Officer Clawback Policy (the "Policy"). Capitalized terms used but not otherwise defined in this Acknowledgement Form (this "Acknowledgement Form") shall have the meanings ascribed to such terms in the Policy.

By signing this Acknowledgement Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Erroneously-Awarded Compensation (as defined in the Policy) to the Company to the extent required by, and in a manner permitted by, the Policy.

Signature

Name

Date