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.