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

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended December 31, 2024

OR

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

OR

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

Date of event requiring this shell company report _____

For the transition period from ____ to ____

Commission file number 001-36578

Enlivex Therapeutics Ltd.
(Exact name of Registrant as specified in its charter)

State of Israel
(Jurisdiction of incorporation or organization)

14 Einstein Street, Ness Ziona, Israel 7403618
(Address of principal executive offices)

Mr. Oren Hershkovitz
Tel: +972.2.6208072
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Facsimile: +972.2.6208070
14 Einstein Street, Ness Ziona, Israel 7403618
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	Trading symbol	Name of each exchange on which registered
Ordinary Shares, par value NIS 0.40 per share	ENLV	Nasdaq Capital Market

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

23,650,989 ordinary shares, par value NIS 0.40 per share, as of December 31, 2024

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

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

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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

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

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

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

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

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

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.1D-1(b). ☐

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

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

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

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act)

Yes ☐ No ☒

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INTRODUCTION

Business Description of Enlivex

Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel (including its consolidated subsidiaries, "Enlivex", "we", "us", "our" or the "Company"), is a clinical-stage macrophage reprogramming immunotherapy company, developing Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state. Resetting non-homeostatic macrophages into their homeostatic state is critical for immune system rebalancing and resolution of debilitating and life-threatening conditions. Non-homeostatic macrophages contribute significantly to the severity of diseases. By restoring macrophage homeostasis, Allocetra™ has the potential to provide a novel immunotherapeutic mechanism of action for debilitating and life-threatening clinical indications that are defined as "unmet medical needs," as a stand-alone therapy or in combination with leading therapeutic agents. The Company is focused on osteoarthritis as its main inflammatory indication.

About this Annual Report on Form 20-F

References in this Annual Report on Form 20-F to "U.S. dollars", "dollars", "USD", and "$" are to currency of the United States of America, and references to "NIS" are to New Israeli Shekels. Our audited financial statements included in this Annual Report on Form 20-F have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The functional and presentation currency of the Company in this Annual Report on Form 20-F for the year ended December 31, 2024, or the Annual Report on Form 20-F, is the U.S. dollar.

Unless otherwise indicated, U.S. dollar translations of NIS amounts presented in this Annual Report on Form 20-F are translated using the rate of NIS 3.647 to $1.00, the exchange rate reported by the Bank of Israel on December 31, 2024.

Unless otherwise indicated, information in this Annual Report on Form 20-F concerning economic conditions, our industry, our markets and our competitive position is based on a variety of sources, including information from other independent industry analysts and publications, as well as our own estimates and research. Our estimates are derived from publicly available information released by third-party sources, as well as data from our internal research, which we believe to be reasonable. None of the independent industry publications used in this Annual Report on Form 20-F were prepared on our behalf.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. These forward-looking statements include, but are not limited to:

- our expectations regarding the timing of clinical trials with respect to Allocetra™;
- our expectations regarding the progress of our clinical trials, including the duration, cost and whether such trials will be conducted at all;
- our intention to successfully complete clinical trials in order to be in a position to submit applications for accelerated regulatory paths in the EU and the United States;
- the possibility that we will apply in the future for regulatory approval for our current and any future product candidates we may develop, and the costs and timing of such regulatory approvals;
- the likelihood of regulatory approvals for any product candidate we may develop;
- the timing, cost or other aspects of the commercial launch of any product candidate we may develop, including the possibility that we will build a commercial infrastructure to support commercialization of our current and any future product candidates we may develop;
- future sales of our product candidates or any other future products or product candidates;
- our ability to achieve favorable pricing for our product candidates;
- the potential for our product candidates to receive orphan drug designations;
- that any product candidate we develop potentially offers effective solutions for various diseases;
- whether we will develop any future product candidates internally or through strategic partnerships;
- our expectations regarding the manufacturing and supply of any product candidate for use in our clinical trials, and the commercial supply of those product candidates;
- third-party payer reimbursement for our current or any future product candidates;
- our estimates regarding anticipated expenses, capital requirements and our needs for substantial additional financing;
- patient market sizes and market adoption of our current or any future product candidates by physicians and patients;
- completion and receiving favorable results of clinical trials for our product candidates;
- protection of our intellectual property, including issuance of patents to us by the United States Patent and Trademark Office (the "USPTO"), and other governmental patent agencies;
- our intention to pursue marketing and orphan drug exclusivity periods that are available to us under regulatory provisions in certain countries;
- the development and approval of the use of our current or any future product candidates for any indication;
- our expectations regarding commercial and pre-commercial activities;
- our expectations regarding collaborations, licensing, acquisitions, and strategic operations;
- our liquidity; and
- the impact of the economic, public health, political and security situation in Israel, the U.S. and other countries in which we may operate or obtain approvals for Allocetra™ and any future product candidates.

In some cases, forward-looking statements are identified by terminology such as "may," "will," "could," "should," "expects," "plans," "anticipates," "believes," "intends," "estimates," "predicts," "hope," "targets," "potential," "goal" or "continue" or the negative of these terms or other comparable terminology. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results or performance to differ materially from those suggested in such forward-looking statements. These statements are current only as of the date of this Annual Report on Form 20-F and are subject to known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from those suggested in the forward-looking statements. In addition, historic results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions or that historic results referred to in this Annual Report on Form 20-F would not be interpreted differently in light of additional research, clinical and preclinical trials results. The forward-looking statements contained in this Annual Report on Form 20-F are subject to risks and uncertainties, including those discussed in Item 3.D. "Risk Factors" and in our other filings with the Securities and Exchange Commission (the "SEC"). Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 20-F. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we do not intend to (and expressly disclaim any such obligation to) update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

RISK FACTOR SUMMARY

Our business is subject to numerous risks and uncertainties, including those described in Item 3.D. "Risk Factors." These risks include, but are not limited to the following:

- We are a clinical-stage macrophage reprogramming immunotherapy company with a history of operating losses; we expect to incur additional losses in the future and may never be profitable.
- We have not generated any revenue from Allocetra™ or any other product candidate, and we may never be profitable;
- We will need substantial additional capital in the future; if additional capital is not available, we will have to delay, reduce or cease operations;
- We are unable to estimate our long-term capital requirements due to uncertainties associated with the development and commercialization of our product candidates; if we fail to obtain necessary funds for our operations, we will be unable to develop and commercialize any of our product candidates;
- Due to our recurring operating losses, our ability to continue to operate as a going concern is dependent on additional financial support;
- Our business, operating results and growth may be adversely affected by current or future unfavorable economic and market conditions due to geopolitical tensions and political, economic and military instability;
- We have focused substantially all of our efforts and resources on Allocetra™, and we may not obtain regulatory approval of Allocetra™;
- It is possible that none of our product candidates will achieve commercial success in a timely and cost-effective manner, or ever;
- Results from our clinical trials may be negative or may not replicate the results of our preclinical trials or earlier clinical trials, which could require that we abandon development of Allocetra™, our other product candidates or any future product candidates, which will significantly impair our ability to generate revenues;
- The clinical trial process is complex and expensive, and commencement and completion of clinical trials can be delayed or prevented for a number of reasons;
- We cannot be certain that the results of our potential clinical trials, even if all endpoints are met, will support regulatory approval in any territory, of any of our product candidates for any indication;
- Our manufacturing processes are complex, delicate and susceptible to contamination, and involve biological intermediates that are subject to stringent regulations;
- If we or any potential CMOs we retain in the future fail to comply with manufacturing regulations, our financial results and financial condition could be adversely affected;
- Our product candidates may produce undesirable side effects that we may not detect in our clinical trials, which could prevent us from achieving or maintaining market acceptance of any such product candidate and could substantially increase commercialization costs or even force us to cease operations;
- Even if Allocetra™ or any other product candidate that we may develop receives marketing approval in any territory, we will continue to face extensive regulatory requirements, and any such product may still face future development and regulatory difficulties; in addition, we are subject to government regulations, and we may experience delays in obtaining the required regulatory approvals to market our proposed product candidates;

- Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and any future product candidates;

- We expect the healthcare industry to face increased limitations on reimbursement, rebates and other payments as a result of healthcare reform, which could adversely affect third-party coverage of our products and how much or under what circumstances healthcare providers will prescribe or administer our products;

- Significant disruptions of information technology systems, cyberattacks and other security breaches could compromise our proprietary and confidential information, which could harm our business and reputation;

- If product liability lawsuits are successfully brought against us, our insurance may be inadequate;

- We manage our business through a small number of senior executive officers, and we depend on them even more than similarly situated companies;

- We depend on third parties to conduct our clinical trials;

- We intend to rely primarily on third parties to market and sell Allocetra™ and any other product candidate;

- Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and any future product candidates;

- The failure to obtain or maintain patents, licensing agreements and other intellectual property could impact our ability to compete effectively; and

- We cannot predict the scope and extent of patent protection for our product candidates because the patent positions of pharmaceutical products are complex and uncertain.

PART ONE

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

3.A. [Reserved]

3.B. Capitalization and Indebtedness

Not applicable.

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

Not applicable.

3.D. Risk Factors

Investing in our ordinary shares involves a high degree of risk. You should carefully consider the risks described below before investing in our ordinary shares.

There are a number of risks and uncertainties that could affect our business and cause our actual results to differ from past performance or expected results. We consider the following risks and uncertainties to be those material to our business. If any of these risks actually occur, our business, financial condition and results of operations could suffer, and the trading price of our ordinary shares could decline. We urge investors to consider carefully the risk factors described below, together with the other information contained in this Annual Report on Form 20-F, in evaluating any investment in our ordinary shares.

Risks Related to Our Financial Position and Capital Requirements

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

We are a clinical-stage macrophage reprogramming immunotherapy company with a limited operating history and no currently approved products. To date, we have focused almost exclusively on developing our product candidate, Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic stage, currently focusing on treatment of osteoarthritis. We have funded our operations to date primarily through proceeds from public and private offerings of ordinary shares, warrants and convertible debt. We have no saleable products and have not generated any revenue from product sales. We have incurred losses in each year since our inception in 2005. Our loss attributable to holders of our ordinary shares for the years ended December 31, 2024 and 2023 was $15 million and $29 million, respectively. As of December 31, 2024, we had an accumulated deficit of approximately $127.1 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs and from general and administrative costs.

We expect to continue to incur significant research and development expenses in the future as we continue the advancement of our clinical studies and as we potentially pursue additional indications. We may also incur expenses in connection with third-party studies and trials involving our product candidates or other intellectual property. In addition, if we obtain marketing approval for any of our product candidates, we will likely initially incur significant outsourced sales, marketing and manufacturing expenses, as well as continued research and development expenses. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing cell immunotherapy products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We have not generated any revenue from Allocetra™ or any other product candidate, and we may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue in excess of our expenses. We have not generated any revenue from our development of Allocetra™, or any other product candidate. We do not know when, or if, we will generate any revenue. We do not expect to generate revenue unless and until we obtain regulatory and marketing approval of, and commercialize, Allocetra™ or any other product candidate. We will continue to incur research and development and general and administrative expenses related to our operations. We expect to continue to incur losses for the foreseeable future, and such losses will likely increase as we:

- initiate and manage preclinical development and clinical trials for our current and any new product candidates;
- seek regulatory approvals for our product candidates, or future product candidates, if any;
- implement internal systems and infrastructure (including, without limitation, hiring of additional personnel, as needed) to develop sales and marketing functions, if and when our product candidate receives applicable regulatory approval;
- seek to in-license additional technologies for development, such as cell delivery, processing and testing technologies;
- hire additional management and other personnel; and
- move towards commercialization of our product candidates and future product candidates, if any.

We may out-license our ability to generate revenue from our product candidates, depending on a number of factors, including our ability to:

- obtain favorable results from and progress the clinical development of our product candidates, particularly Allocetra™;
- develop and obtain regulatory approvals in various countries and for the uses we intend to pursue for our product candidates;
- subject to successful completion of registration, clinical trials and perhaps additional clinical trials of any product candidate, apply for and obtain marketing approval in the countries we intend to pursue for such product candidate;
- contract for the manufacture of commercial quantities of our product candidates at acceptable cost levels, subject to the receipt of marketing approval; and
- establish external, and potentially, internal, sales and marketing capabilities to effectively market and sell our product candidates in the United States and other countries.

Even if Allocetra™, our lead product candidate, which is currently being developed for osteoarthritis, is approved for commercial sale for any indication, it may not gain market acceptance or achieve commercial success. In addition, we anticipate incurring significant costs associated with commercialization. We may not achieve profitability soon after generating product revenue, if ever. If we are unable to generate product revenue, we would not become profitable and would be unable to continue operations without additional funding.

We will need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

We will need to raise substantial additional capital to fund our operations and to develop and commercialize our current product candidate, Allocetra™, or any future product candidate. Our future capital requirements may be substantial and will depend on many factors, including, but not limited to:

- our clinical trial results;
- the cost, timing and outcomes of seeking marketing approval of our product candidates;
- the costs associated with commercializing our product candidates if we receive marketing approval, including the cost and timing of establishing external, and potentially in the future, internal, sales and marketing capabilities to market and sell such product candidates;
- subject to receipt of marketing approval, revenue received from sales of approved products, if any, in the future;
- the demand for our products, if any;
- the cost of filing and prosecuting patent applications and the cost of defending our patents;
- the cost of prosecuting infringement actions against third parties;
- exploration and possible label expansion of our product candidates for the treatment of other conditions or indications;
- any product liability or other lawsuits related to our future product candidates or products, if any;
- the expenses needed to attract and retain skilled personnel; and
- the costs associated with being a public company.

Based on our current operating plan, we anticipate that our existing resources will be sufficient to maintain our currently planned operations, including our continued product development, through the end of 2026. We will require significant additional funds to initiate and complete the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA") approval process. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, including, without limitation, regulatory requests by the FDA or EMA, changes in our development strategy, delays in or an inability to execute our development plans, unsuccessful preclinical or clinical studies and losing our "Small and Medium Enterprise" status at the EMA, which entitles us to significant fee reductions. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital and operating expenditures associated with our anticipated clinical trials and general operations. We have no committed external sources of funds. Additional financing may not be available when we need it or on terms that are favorable to us. If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay planned clinical trials or other development activities for our product candidates, which would materially and adversely affect our liquidity and results of operations.

Raising additional financing may be costly or difficult to obtain, may dilute current shareholders' ownership interests and may require that we relinquish our rights to certain of our technologies, products or marketing territories.

Any debt or equity financing that we may need may not be available on terms favorable to us, or at all. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our technologies, products or marketing territories. If we are unable to obtain the required additional capital, we may have to curtail our growth plans or cut back on existing business, and we may not be able to continue operating.

We may incur substantial costs in pursuing future financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition and results of operations.

Any additional capital raised through the sale of equity or equity-linked securities may dilute our current shareholders' ownership in us and could also result in a decrease in the market price of our ordinary shares. The terms of the securities issued by us in future capital transactions may be more favorable to new investors and may include the issuance of warrants or other derivative securities, which may have a further dilutive effect.

We have not yet commercialized any products and we may never become profitable.

We have not yet commercialized any products, and we may never do so. We do not know when or if we will complete any of our product development efforts, obtain regulatory approval for any product candidates or successfully commercialize any approved products. Even if we are successful in developing products that are approved for marketing, we will not be successful unless these products gain market acceptance for appropriate indications. The degree of market acceptance of any of our planned future products will depend on a number of factors, including, but not limited to:

- the timing of regulatory approvals in the countries, and for the uses, we intend to pursue with respect to the commercialization of our product candidates;
- the competitive environment;
- the acceptance by the medical community of the safety and clinical efficacy of our products and their potential advantages over other therapeutic products;
- the adequacy and success of distribution, sales and marketing efforts, including through strategic agreements with pharmaceutical and biotechnology companies; and
- the pricing and reimbursement policies of government and third-party payors, such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, patients, third-party payors or the medical community in general may be unwilling to accept, utilize or recommend coverage of, and in the case of third-party payors, cover, any of our product candidates. As a result, we are unable to predict the extent of future losses or the time required to achieve profitability, if at all. Even if we successfully develop one or more products, we may not become profitable.

We are unable to estimate our long-term capital requirements due to uncertainties associated with the development and commercialization of our product candidates. If we fail to obtain necessary funds for our operations, we will be unable to develop and commercialize any of our product candidates.

We expect our long-term capital requirements to depend on many potential factors, including, among others:

- the number of product candidates in development;
- the duration and cost of discovery and preclinical development;
- the regulatory path of product candidates, including our lead product candidate, Allocetra™, which is being developed for osteoarthritis;
- the results of preclinical and clinical testing, which can be unpredictable in product candidate development;

- our ability to successfully commercialize our product candidates, including securing commercialization and out-licensing agreements with third parties and favorable pricing and market share;

- the progress, success and costs of our clinical trials and research and development programs, including those associated with milestones and royalties;

- the costs, timing and outcome of regulatory review and obtaining regulatory approval of our lead product candidate and addressing regulatory and other issues that may arise post-approval;

- the breadth of the labeling, assuming that any of our product candidates are approved for commercialization by the relevant regulatory authority;

- our need or decision to acquire or in-license complementary technologies or new platform technologies or product candidate targets;

- the costs of enforcing our issued patents and defending intellectual property-related claims;

- the costs of investigating patents that might block us from developing potential product candidates;

- the costs of recruiting and retaining qualified personnel;

- our revenue, if any; and

- our consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated.

If we are unable to obtain the funds necessary for our operations, we will be unable to develop and commercialize any of our product candidates, or any future product candidates, which would materially and adversely affect our business, liquidity and results of operations.

Due to our recurring operating losses, our ability to continue to operate as a going concern is dependent on additional financial support.

We devote substantially all of our efforts toward research and development activities. In the course of such activities, we have sustained operating losses and expect such losses to continue for the foreseeable future. We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, the FDA, EMA or other regulatory authorities approve one of our product candidates and we successfully commercialize (including out-licensing) such product candidate. Based on our current operating plan, we anticipate that our existing resources will be sufficient to maintain our currently planned operations, including our continued product development, through the end of 2026. Accordingly, our ability to continue operating will require us to obtain additional financing to fund our operations and we cannot provide any assurance that we will be successful in doing so. If we are not successful in obtaining additional capital resources, we may not be able to continue our activities beyond the end of 2026. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in loss of confidence by investors, suppliers and employees.

Our limited operating history makes it difficult to evaluate our business and prospects.

Although we have been in existence since 2005, we have a limited operating history, and our operations to date have been limited primarily to research and development, clinical trials, raising capital and recruiting scientific and management personnel. Therefore, it is difficult to evaluate our business and prospects. We have not yet commercialized or obtained regulatory approval for any product candidate. Consequently, any predictions about our future performance may not be accurate, and you may not be able to fully assess our ability to complete development or commercialize our product candidates, or any future product candidates, obtain regulatory approvals or achieve market acceptance or favorable pricing for our product candidates or any future product candidates.

Our business, operating results and growth may be adversely affected by current or future unfavorable economic and market conditions due to geopolitical tensions and political, economic and military instability.

Our business depends on the economic health of the global economies. U.S. and global markets have recently experienced volatility and disruption, including as a result of the escalation of geopolitical tensions following the start of the war between Russia and Ukraine in February 2022 and the war between Israel and Hamas in October 2023. In addition, there is current uncertainty about the future relationship between the United States and other countries with respect to trade policies, taxes, government regulations and tariffs and we cannot predict whether, and to what extent, U.S. trade policies will change in the future. 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, terrorism or other geopolitical events, such as military or political instability in Israel or changes in U.S. relations with other countries, 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 a challenging capital raising environment, slower adoption of new technologies and increased competition, and any such disruptions may also magnify the impact of other risks described in this Annual Report on Form 20-F. See also "Risks Related to Israeli Law and Our Operations in Israel—*Our headquarters and other significant operations are located in Israel and, therefore, our business and operations may be adversely affected by political, economic and military instability in Israel."*

Risks Related to Our Business, Industry and Regulatory Requirements

We have focused substantially all of our efforts and resources on Allocetra™, and we may not obtain regulatory approval of Allocetra™.

We have focused substantially all of our efforts and financial resources in the research and development of Allocetra™. As a result, our business is primarily dependent on our ability to complete the development of, obtain regulatory approval for, and successfully commercialize Allocetra™. The process to develop, obtain regulatory approval for and commercialize Allocetra™ is long, complex and costly, and its outcome is uncertain.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drugs and pharmaceutical products, including biologics, are subject to extensive regulation by the FDA, the EMA and regulatory agencies in other countries. These regulations differ from jurisdiction to jurisdiction. We are not permitted to market Allocetra™, or any other product candidate, in the United States until we receive approval of a biologics license application ("BLA") from the FDA, or in the European Union until we receive a marketing authorization application ("MAA") from the EMA, or in any foreign countries until we receive the requisite approval from the respective regulatory agencies in such countries. We have not yet obtained regulatory clearance to conduct confirmatory clinical trials that are necessary to file a BLA with the FDA or comparable applications to other regulatory authorities in other countries, nor have we received marketing approval for Allocetra™ in any country. The results of clinical trials may be unsatisfactory and, even if endpoints are successfully met, the FDA, EMA, or other regulatory authorities, may not approve our marketing application should we be in a position to file one.

Marketing approval procedures and timelines vary among countries and can involve additional product testing and additional administrative review periods. The approval process may include the risks detailed above, as well as other risks. In some countries and in specific programs, product approval depends on showing superiority to an approved alternative therapy. This can result in significant expenses for conducting complex clinical trials. In addition, time from approval to commercialization may significantly differ between countries. In particular, in many countries outside the United States, it is required that a product receives pricing and reimbursement approval before it can be commercialized. This can result in substantial delays in such countries. If we fail to comply with regulatory requirements in the United States or international markets or to obtain and maintain required approvals or if regulatory approvals in the United States or international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Marketing approval in one jurisdiction does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for Allocetra™ or any other product candidate. This would reduce our target market and limit the full commercial potential of Allocetra™ or any other product candidate.

It is possible that none of our product candidates will achieve commercial success in a timely and cost-effective manner, or ever.

Even if regulatory authorities approve any of our product candidates, they may not be commercially successful. Our product candidates may not be commercially successful because, among other things, government agencies or other third-party payors may not provide reimbursement for the costs of the product, or the reimbursement may be too low to be commercially successful. Also, physicians and others may not use or recommend our product candidates, even following regulatory approval. In addition, a product approval, even if issued, may limit the uses for which such product may be distributed, which could adversely affect the commercial viability of the product. Moreover, third parties may develop superior products or have proprietary rights that preclude us from marketing our product. Physician and patient acceptance of, and demand for, our products, if we obtain regulatory approval, will depend largely on many factors, including, but not limited to, the extent, if any, of reimbursement of costs by government agencies and other third-party payors, pricing, the effectiveness of our marketing and distribution efforts, the safety and effectiveness of alternative products, and the prevalence and severity of side effects associated with such products. If physicians, government agencies and other third-party payors do not accept the use or efficacy of our products, we will not be able to generate significant revenue, if any.

Results from our clinical trials may be negative or may not replicate the results of our preclinical trials or earlier clinical trials, which could require that we abandon development of Allocetra™, our other product candidates or any future product candidates, which will significantly impair our ability to generate revenues.

Upon the completion of any clinical trial, the results might not support the outcomes sought by us. Further, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the completed preclinical studies and clinical trials for Allocetra™ may not be predictive of the results we may obtain in later stage trials of Allocetra™ or clinical trials of any of our other product candidates. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies. and clinical trials have nonetheless failed to obtain approval by the FDA, EMA, or other regulatory agency, for their products.

In addition, the clinical trial process may fail to demonstrate that Allocetra™ is safe and effective for its indicated uses. Any such failure may cause us to abandon Allocetra™ and may delay development of other product candidates. Any delay in, or termination or suspension of, our clinical trials will delay the requisite filings with the FDA, EMA or other regulatory agencies and, ultimately, our ability to commercialize our product candidates and generate revenues. If the clinical trials do not support our product claims, the completion of development of such product candidate may be significantly delayed or abandoned, which will significantly impair our ability to generate revenues and will materially adversely affect our results of operations.

The clinical trial process is complex and expensive, and commencement and completion of clinical trials can be delayed or prevented for a number of reasons.

We may not be able to commence or complete the clinical trials required to support our submission of a BLA to the FDA or a MAA to the EMA or any similar submission to regulatory authorities in other countries. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. The fact that the FDA, EMA or other regulatory authorities permit a company to conduct human clinical trials is no guarantee that the trial will be successful. On the contrary, most product candidates that enter clinical trials do not prove to be successful and do not result in the filing of a BLA, MAA or similar filing. Drug candidates that prove successful at one clinical trial phase may prove unsuccessful at a subsequent phase. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements and in part because the results of clinical trials are inherently uncertain and unpredictable. Regulatory authorities, such as the FDA and EMA, may preclude clinical trials from proceeding. Additionally, the clinical trial process is time-consuming, and failure can occur at any stage of the trials. We may encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- difficulties obtaining regulatory clearance or approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;

- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), pharmaceutical shipping companies and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, CMOs, shipping companies and trial sites;

- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;

- difficulties in obtaining institutional review board ("IRB") approval to conduct a clinical trial at a prospective site;

- delays resulting from a decision of the FDA or EMA not to review a BLA or MAA for Allocetra™, respectively, or any of our other product candidates, under the FDA's Fast Track Development Program or as a Breakthrough Therapy; and

- challenges in recruiting and enrolling patients or donors to participate in clinical trials for a variety of reasons, including size and nature of patient population, proximity of patients to clinical sites, eligibility criteria for the trial, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, EMA or other regulatory authorities, the IRBs at the sites where such boards are overseeing a trial, or a Data and Safety Monitoring Board ("DSMB") overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;

- unforeseen safety issues or lack of effectiveness; and

- lack of adequate funding to continue the clinical trials.

Even when clinical trials are designed for patients to be randomized with comparable attributes across the treatment and placebo groups, significant imbalances in patient attributes across patient subgroups could make it challenging to analyze the efficacy of our product candidates. For example, in our Phase II trial evaluating Allocetra™ in patients with sepsis, the randomization resulted in the Allocetra™-treated cohorts having 20% higher frequency of septic shock and 35% higher frequency of invasive ventilation prior to treatment, as compared with the control group. Both of these patient attributes are associated with a significantly higher degree of difficulty of treatment and higher mortality rates. These imbalances made it challenging to deduce the relative effect in other patient subgroups.

In addition, we or regulatory authorities may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks, or if others report that similar products pose an unacceptable risk to patients, or if the regulatory authorities find deficiencies in our regulatory submissions or the conduct of such trials. Any suspension of clinical trials will delay possible regulatory approval, if any, and adversely affect our ability to develop products and generate revenue.

Obtaining approval of a BLA, MAA or other regulatory approval, even after clinical trials that are believed to be successful is an uncertain process.

Even if we complete our planned clinical trials and believe the results to be successful, all of which are uncertain, obtaining approval of a BLA, or similar regulatory application, is an extensive, lengthy, expensive and uncertain process, and the EMA, the Israeli Ministry of Health ("IMOH"), the FDA and other regulatory agencies may delay, limit or deny approval of our product candidates for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the applicable regulatory agencies that our product candidates are safe and effective for any indication;
- the results of our clinical trials may not meet the level of statistical significance or clinical significance required by the applicable regulatory agencies for approval;
- the applicable regulatory agencies may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the applicable regulatory agencies may not find the data from preclinical studies and clinical trials sufficient to demonstrate that our product candidates' clinical and other benefits outweigh their respective safety risks;
- the applicable regulatory agencies may disagree with our interpretation of data from preclinical studies or clinical trials;
- the applicable regulatory agencies may not accept data generated at our clinical trial sites;
- the data collected from preclinical studies and clinical trials of our product candidates may not be sufficient to support the submission of a BLA or similar regulatory application;
- the applicable regulatory agencies may not schedule an advisory committee meeting in a timely manner, or the advisory committee may recommend against approval of our application or may recommend that the applicable regulatory agencies require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the applicable regulatory agencies may require development of a risk evaluation and mitigation strategy as a condition of approval;
- the applicable regulatory agencies may require simultaneous approval for both adults and children which would delay needed approvals, or we may have successful clinical trial results for adults, but not children, or vice versa;
- the applicable regulatory agencies may change their approval policies or adopt new regulations that may impede consideration or approval of our BLA, or similar regulatory application;
- the applicable regulatory agencies may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers, or suppliers of blood and cell samples or providers of cell collection, freezing and transportation services, with which we enter into agreements for clinical and commercial supplies; and
- the applicable regulatory agencies may demand post-marketing approval studies, such as Phase IV clinical trials, in connection with our product candidates.

Phase III clinical trials frequently produce unsatisfactory results even though prior clinical trials were successful. Therefore, the results of the additional trials that we conduct may or may not be successful. The applicable regulatory agencies may suspend all clinical trials or require that we conduct additional clinical, nonclinical, manufacturing, validation or drug product quality studies and submit those data before considering or reconsidering the marketing application, or similar regulatory application. Depending on the extent of these, or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the applicable regulatory agencies to provide regulatory approval. If any of these outcomes occur, we likely would not receive approval for Allocetra™, or any of our other product candidates, and may be forced to cease operations.

Even if we obtain regulatory approval for Allocetra™, or any of our other product candidates, the approval might contain significant limitations related to the intended uses for which the product is approved, including, without limitation, restrictions related to certain labeled populations, age groups, warnings, precautions or contraindications, or an approval may be subject to significant post-marketing studies or risk mitigation requirements. If we are unable to successfully commercialize Allocetra™, or any of our other product candidates, we may be forced to cease operations.

Changes in regulatory requirements and guidance or unanticipated events during our clinical trials may occur, which may result in necessary changes to clinical trial protocols, which could result in increased costs to us, delay our development timeline or reduce the likelihood of successful completion of our clinical trials.

Changes in regulatory requirements and guidance or unanticipated events during our clinical trials may occur, and as a result, we may need to amend our clinical trial protocols. Amendments may require us to resubmit our clinical trial protocols to IRBs for review and approval, which may adversely affect the cost, timing and successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, any of our clinical trials, the commercial prospects for our affected product candidates would be harmed and our ability to generate product revenue would be delayed, possibly materially.

Our manufacturing processes are complex, delicate and susceptible to contamination, and involve biological intermediates that are subject to stringent regulations.

Blood is a raw material that is susceptible to damage and contamination and may contain human pathogens, any of which would render the blood unsuitable as raw material for further manufacturing. For instance, improper storage of blood, by us or third-party suppliers, may require us to destroy some of our raw material. If unsuitable blood is not identified and discarded prior to the release of the blood to the manufacturing process, it may be necessary to discard intermediate or finished product made from that blood or to recall any finished product released to the market or individual patients, resulting in a charge to cost of goods sold.

The manufacture of Allocetra™ is a complex and delicate process of cell collection, separation, freezing, storing, incubation, harvesting, formulating and testing, each under aseptic conditions. First, cells are collected by separation from blood donations at collection centers and medical centers. Donations for Allocetra™ are collected from healthy donors through apheresis. The cells sourced for Allocetra™ are then shipped to a manufacturing site for cryopreservation by trained personnel pursuant to current Good Manufacturing Practices ("cGMP") requirements, FDA guidelines and our manufacturing protocol, as detailed in our Chemistry Manufacturing and Controls ("CMC") protocols. Second, the cells are thawed, processed, prepared in an intravenous bag and tested according to our quality assurance and quality control assays and cGMP requirements. The final product is then shipped to the clinical site where it is infused into the patient within the predetermined expiration period. All shipping and handling are pursuant to carefully controlled conditions, including controlled temperatures, as required by applicable regulations. The manufacturing sites must be registered manufacturing facilities operating under cGMP requirements and all manufacturing activities, including cell collection, processing, testing, freezing, shipping, final product preparations, packaging and labeling, must be conducted by properly and adequately trained personnel in accordance with detailed protocols, batch records and our CMC and based on cGMP requirements and FDA, or other applicable regulatory, guidelines.

Allocetra™, and our other potential drug candidates, if any, may fail to meet our stringent specifications through a failure in one or more of these process steps. Such failure would prohibit us from releasing the drug at issue for human use until the failure is properly and sufficiently corrected and resolved. We may detect instances in which an unreleased product was produced, either internally (as is the case for small scale preclinical or early stage clinical production) or by a CMO (as would be the case for large scale production for which we would provide appropriate technology training and require EMA or FDA approval), without adherence to our manufacturing procedures or blood used in our production process was not collected, shipped, processed or stored in a compliant manner consistent with our current cGMP, or other regulations or regulatory requests, including those by the EMA. Such an event of non-compliance would likely result in our determination that the implicated product candidates should not be released and therefore should be destroyed. Even if handled properly, biologics may form or contain particulates or have other issues or problems after storage which may require destruction or recalls. The impact of such non-compliance or issues or problems would be exacerbated if our manufacturing efforts are scaled to conduct a Phase II or Phase III clinical trial in Europe, Israel or the United States, where there may be numerous collection sites and where shipments may be made to multiple locations with large numbers of patients across a large geographical area. There can be no assurance that we can scale such a manufacturing process, including in Europe, Israel and the United States, in a cost-effective or efficient manner, or in a manner that will meet all regulatory requirements, including EMA, IMOH or FDA requirements, if at all.

While we expect to write-off small amounts of work-in-progress in the ordinary course of business due to the complex nature of blood, our processes and our product candidates, unanticipated events may lead to write-offs and other costs materially in excess of our expectations and the reserves we have established for these purposes. Such write-offs and other costs could cause material fluctuations in our liquidity and results of operations. Furthermore, contamination of our product candidates could cause consumers or other third parties with whom we conduct business to lose confidence in the reliability of our manufacturing procedures, which could adversely affect our liquidity and results of operations. In addition, faulty or contaminated product candidates that are unknowingly distributed could result in patient harm, threaten the reputation of our products.

If we or any potential CMOs we retain in the future fail to comply with manufacturing regulations, our financial results and financial condition could be adversely affected.

Before a marketing application is approved, or before we begin the commercial manufacture of any of our products, CMOs and other outsourced manufacturing service providers we may engage must obtain regulatory approval of their manufacturing facilities, processes and quality systems. In addition, pharmaceutical manufacturing facilities are continuously subject to inspection by EMA and foreign regulatory authorities before and after product approval. Due to the complexity of the processes used to manufacture pharmaceutical products and product candidates, any potential third-party manufacturer may be unable to continue to pass or initially pass federal, state or international regulatory inspections in a cost-effective manner.

The EMA and foreign regulators require manufacturers to register manufacturing facilities. The EMA and foreign regulators also inspect these facilities to confirm compliance with requirements that the EMA or foreign regulators establish. We, to the extent we may manufacture our products in the future, or our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the EMA's or foreign regulators' requirements necessary to continue manufacturing our product candidate. Any failure to comply with EMA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop and market our product candidate and any future product candidates.

If a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of our products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our financial results and financial condition.

Our ability to produce safe and effective products depends on the safety of our blood supply against transmittable diseases.

Despite overlapping safeguards, including the screening of donors and GMP aseptic manufacturing under a quality controlled governing system, the risk of transmissible disease through blood products cannot be entirely eliminated. For example, because blood-derived therapeutics involve the use and purification of human blood, there has been concern raised about the risk of transmitting human immunodeficiency virus ("HIV"), West Nile virus, H1N1 virus or "swine flu" and other blood-borne pathogens and infectious agents through blood-derived products. There are also concerns about the future transmission of H5N1 virus, or "bird flu." In the 1980s, thousands of individuals with hemophilia worldwide became infected with HIV through contaminated Factor VIII blood-derived products.

New infectious diseases emerge in the human population from time to time. If a new infectious disease has a period during which time the causative agent is present in the bloodstream, but symptoms are not present, it is possible that blood donations could be contaminated by that infectious agent. Typically, early in an outbreak of a new disease, tests for the causative agent do not exist. During this early phase, we must rely on screening of donors and patients (e.g., for behavioral risk factors or physical symptoms) to reduce the risk of blood contamination. Screening methods are generally less sensitive and specific than a direct test as a means of identifying potentially contaminated blood units.

During the early phase of an outbreak of a new infectious disease, our ability to manufacture safe products would depend on the manufacturing process' capacity to inactivate or remove the infectious agent. To the extent that a product's manufacturing process is inadequate to inactivate or remove an infectious agent, our ability to manufacture and distribute that product would be impaired.

If a new infectious disease were to emerge in the human population, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to procure blood, manufacture our product candidates or both. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for blood-derived products.

In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected blood. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the blood used in the production of our product candidates.

Our product candidates may produce undesirable side effects that we may not detect in our clinical trials, which could prevent us from achieving or maintaining market acceptance of any such product candidate and could substantially increase commercialization costs or even force us to cease operations.

Even if Allocetra™, or any of our other product candidates, receives marketing approval, we or others may later identify undesirable side effects caused by the product, and, in that event, a number of potentially significant negative consequences could result, including, without limitation:

- regulatory authorities may suspend or withdraw their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications or distribution and use restrictions, or they may require that these statements be placed in a black box on the product's labeling;
- regulatory authorities may require us to issue specific communications to healthcare professionals, such as "Dear Doctor" letters;
- regulatory authorities may issue negative publicity regarding the affected product, including safety communications;
- we may be required to change the way the product is administered, conduct additional preclinical studies or clinical trials or restrict or cease the distribution or use of the product; and
- we could be sued and held liable for harm caused to patients, and in certain cases, certain relatives.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase commercialization costs or even force us to cease operations.

Even if Allocetra™ or any other product candidate that we may develop receives marketing approval, we will continue to face extensive regulatory requirements, and any such product may still face future development and regulatory difficulties. In addition, we are subject to government regulations, and we may experience delays in obtaining the required regulatory approvals to market our proposed product candidates.

Even if we receive regulatory approval to market a particular product candidate, any such product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the uses for which the product may be marketed or the conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, which could adversely affect us by reducing revenues or increasing expenses, and cause the approved product candidate not to be commercially viable. In addition, as clinical experience with a drug expands after approval, typically because it is used by a greater number and more diverse group of patients after approval than during clinical trials, side effects and other problems may be observed over time after approval that were not seen or anticipated during pre-approval clinical trials or other studies. Any adverse effects observed after the approval and marketing of a product candidate could result in limitations on the use of or withdrawal of any approved products from the marketplace. The absence of long-term safety data may also limit the approved uses of our products, if any. If we fail to comply with the regulatory requirements of the EMA, and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including, without limitation, the following:

- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- refuse to approve pending applications or supplements to applications;
- suspend any ongoing clinical trials;
- suspend or withdraw marketing approval;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- seize or detain products;
- ban or restrict imports and exports;
- issue warning letters or untitled letters; or
- refuse to approve pending applications or supplements to applications.

In addition, various aspects of our operations are subject to federal, state or local laws, rules and regulations, any of which may change from time to time. Costs arising out of any regulatory developments could be time-consuming and expensive and could divert management resources and attention and, consequently, could adversely affect our business operations and financial performance.

Delays in regulatory approval, limitations in regulatory approval and withdrawals of regulatory approval may have a material adverse effect on the Company.

If we receive marketing approval for any of our product candidates, sales will be limited unless the product achieves broad market acceptance.

The commercial success of Allocetra™ or any future product candidate for which we obtain marketing approval from the FDA, EMA or other regulatory authorities, will depend on the breadth of its approved labeling and upon the acceptance of the product by the medical community, including physicians, patients and third-party payors. The degree of market acceptance of any approved product will depend on a number of factors, including, without limitation:

- demonstration of clinical safety and efficacy compared to other products;

- ability of physicians to accurately diagnose the targeted indications;
- the relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in the product's approved labeling;
- distribution and use restrictions imposed by the EMA, or other regulatory agencies, or agreed to by us as part of a mandatory or voluntary risk management plan;
- availability of alternative treatments, including a number of competitive products already approved or expected to be commercially launched in the near future;
- pricing and cost effectiveness;
- the effectiveness of our, or any future collaborators', sales and marketing strategies;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- the willingness of patients to pay for drugs out of pocket in the absence of third-party coverage.

If any of our product candidates is approved but does not achieve an adequate level of acceptance by physicians, third-party payors and patients, we may not generate sufficient revenue from the product, and we may not become profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of the product may require significant resources and may never be successful.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and any future product candidates.

We may determine to seek collaboration arrangements in the future with pharmaceutical or biotechnology companies for the development and commercialization of Allocetra™ and any future product candidates. For example, we plan to seek potential external collaboration or out-licensing opportunities for the continued clinical development of Allocetra™ for use in patients with sepsis instead of pursuing internal development. We will face, to the extent that we decide to enter into future collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements. Additionally, the terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements, if any, would depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. For example, we may not be able to control the amount and timing of resources that the collaboration partner devotes to the product development or marketing programs, the collaboration partner may experience financial difficulties, or we may be required to relinquish important rights such as marketing, distribution, and intellectual property rights.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve.

Collaborations with pharmaceutical or biotechnology companies and other third parties are often terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

We cannot be certain that, following a collaboration, strategic transaction or license, we will achieve the results, revenue, or specific net income that justifies such transaction.

If we acquire or in-license additional technologies or product candidates, we may incur additional costs, have integration difficulties and experience other risks that could harm our business and results of operations.

We may acquire or in-license additional product candidates and technologies. Any product candidate or technologies we in-license or acquire will likely require additional development efforts prior to commercial sales, including extensive preclinical or clinical testing, or both, and approval by the FDA, EMA and applicable foreign regulatory authorities, if any. All product candidates are prone to risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate, or products developed based on in-licensed technology, will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any product candidate that we develop based on acquired or in-licensed technology that is granted regulatory approval will be manufactured or produced economically, successfully commercialized or widely accepted or competitive in the marketplace. Moreover, integrating any newly acquired or in-licensed product candidates could be expensive and time-consuming. If we cannot effectively manage these aspects of our business strategy, our business may not succeed.

The FDA, EMA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA, EMA and other regulatory agencies strictly regulate promotional claims about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA, EMA or other regulatory agencies as reflected in the product's approved labeling. In particular, any labeling approved by such regulatory agencies for our products, if any, may also include restrictions on use. Such regulatory agencies may impose further requirements or restrictions on the distribution or use of our products as part of a mandatory plan, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. If we receive marketing approval for our product candidates, physicians may nevertheless prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such "off-label" uses, we may become subject to significant liability. In particular, the U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The EMA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

We may be subject to extensive environmental, health and safety, and other laws and regulations in multiple jurisdictions.

Our business involves the controlled use, including through our service providers, of hazardous materials, various biological compounds and chemicals; therefore, we, our agents and our service providers may be subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, the use, management and disposal of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. The risk of accidental contamination or injury from these materials cannot be eliminated. If an accident, spill or release of any regulated chemicals or substances occurs, we could be held liable for resulting damages, including for investigation, remediation and monitoring of the contamination, including natural resource damage, the costs of which could be substantial. We may incur substantial capital costs and operating expenses and may be required to obtain consents to comply with any environmental and health laws or regulations and the terms and conditions of any permits required pursuant to such laws and regulations, including costs incurred by us to install new or updated pollution control equipment for our service providers, modify our operations or perform other corrective actions at our facilities or the facilities of our service providers. In addition, fines and penalties may be imposed on us, our agents and/or our service providers for non-compliance with environmental, health and safety and other laws and regulations or for the failure to have, or comply with the terms and conditions of, required environmental or other permits or consents.

We expect the healthcare industry to face increased limitations on reimbursement, rebates and other payments as a result of healthcare reform, which could adversely affect third-party coverage of our products and how much or under what circumstances healthcare providers will prescribe or administer our products.

In Europe, the United States and in other countries, sales of our products, if any, will depend in part upon the availability of reimbursement from third-party payors, which include governmental authorities, managed care organizations and other private health insurers. Third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

Increasing expenditures for healthcare have been the subject of considerable public attention in Europe and the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the European and U.S. healthcare systems have been introduced or proposed, including reducing reimbursement for prescription products and reducing the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products.

Although we cannot predict the full effect on our business of the implementation of existing legislation or the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for, or restrict coverage of, our products could adversely affect how much or under what circumstances healthcare providers will prescribe or administer our products. This could materially and adversely affect our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

It will be difficult for us to profitably sell our future products, if any, if reimbursement for any such product is limited by government authorities and third-party payor policies.

In addition to any healthcare reform measures that may affect reimbursement, market acceptance and sales of our future products, if any, will depend on the reimbursement policies of government authorities and third-party payors. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the European and U.S. healthcare industries, as well as elsewhere, is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for our future products, if any, and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. In addition, third-party payors are likely to impose strict requirements for reimbursement in order to limit off-label use of a higher priced drug or treatment. Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a 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 coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. We may not be able to provide sufficient data to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for our future products. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only to limited levels, we may not be able to commercialize our product candidate, or any future product candidates, profitably, or at all, even if approved.

Governments outside the United States tend to impose strict price controls, which may adversely affect our future revenues, if any.

In some countries, particularly the countries comprising the EU, the pricing of pharmaceuticals and certain other therapeutics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

We are subject to anti-kickback laws and regulations. Our failure to comply with these laws and regulations could have adverse consequences for us.

There are extensive international and U.S. federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. Such U.S. federal laws include: the anti-kickback statute, which prohibits certain business practices and relationships, including the payment or receipt of compensation for the generation of business that will be paid by Medicare or other federal healthcare programs; the physician self-referral prohibition, commonly referred to as the Stark Law; the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs; and the Civil Monetary Penalties Law, which authorizes the U.S. Department of Health and Human Services to impose civil penalties administratively for fraudulent or abusive acts. In addition, the Affordable Care Act requires drug manufacturers to report to the government any payments to physicians for consulting services and the like. Many jurisdictions outside the United States have similar anti-kickback, fraud and abuse, and healthcare laws and regulations, and we could be subject to these laws and regulations to the extent that we operate in such jurisdictions.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, monetary penalties, imprisonment, denial of Medicare and Medicaid payments or exclusion from the Medicare and Medicaid programs, or both, and debarment. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to reduce or eliminate waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the Civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. Efforts to ensure compliance with any of these federal, state and other fraud and abuse laws and regulations may involve substantial costs, and a violation of the same could have a material adverse effect on our liquidity and financial condition. An investigation into the use by physicians of any of our products, if ever commercialized, may dissuade physicians from either purchasing or using them, and could have a material adverse effect on our ability to commercialize those products.

Our market is subject to intense competition. If we are unable to compete effectively, Allocetra™ or any other product candidate that we may develop may be rendered uncompetitive or obsolete.

There are a number of products in development for the treatment or prevention of osteoarthritis and the other autoimmune and inflammatory disorders that we are targeting, such as psoriatic arthritis, or may target in the future, most of which are being developed by companies that are far larger than us, with significantly greater resources and more experience. The FDA has approved several therapies for the treatment of osteoarthritis, including a certain treatment specifically for knee osteoarthritis. Further, our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large, fully integrated, pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. All of these competitors currently engage in, have engaged in or may engage in the future in the development, manufacturing, marketing and commercialization of new pharmaceuticals, some of which may compete with our product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. These companies may have products in development that are superior to Allocetra™ or any other product candidate that we may develop. Key competitive factors affecting the commercial success of Allocetra™ and any other product candidates that we may develop are likely to be efficacy, time of onset, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement. Furthermore, even if Allocetra™ and any other product candidates that we may develop are able to achieve these attributes, and are approved, acceptance of our products may be inhibited by the reluctance of physicians to switch from existing therapies to our products, or if physicians choose to reserve our products for use in limited circumstances.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA, EMA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than us in obtaining FDA, EMA and other marketing approvals for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize, which may render Allocetra™ or any other product candidates that we may develop obsolete or uncompetitive before we can recover the expenses of developing and commercializing the product. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases and disorders we are targeting could render Allocetra™ or any other product candidates that we may develop, uncompetitive or obsolete. If we cannot successfully compete with new or existing products, our marketing and sales will suffer, and we may never be profitable.

Our competitors currently include companies with marketed products and/or an advanced research and development pipeline. If Allocetra™ for the treatment of moderate to severe knee osteoarthritis is approved for commercial sale, it would face competition from existing approved treatments for knee osteoarthritis, many of which may have achieved commercial success. To compete successfully in the market for treatment of osteoarthritis, we need to disrupt currently marketed drugs, meaning that we will have to demonstrate that the relative cost, method of administration, safety, tolerability and efficacy of Allocetra™ provides a better alternative to existing and new therapies. Moreover, several companies have reported the commencement of research projects related to the treatment or prevention of osteoarthritis. We face competition with respect to Allocetra™ for the treatment of osteoarthritis and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide.

Significant disruptions of information technology systems, cyberattacks and other security breaches could compromise our proprietary and confidential information, which could harm our business and reputation.

In the ordinary course of our business, we generate, collect and store proprietary information, including information regarding clinical trial subjects, intellectual property and business information. We rely on sophisticated information technology systems, including software, cloud services and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. The secure storage, maintenance, and transmission of and access to this information is important to our operations, including our research and development efforts, and reputation. The future operation, success and growth of our business depends on streamlined processes made available through our uninhibited access to information systems, global communications, internet activity and other network processes. Further, because certain employees are working remotely, our reliance on our third-party information technology systems has increased, which could increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations.

Like most other companies, despite our current security measures and process controls, our information technology systems, and those of our third-party service providers, may be vulnerable to information security breaches, ransomware or extortion, mishandled data, acts of vandalism, computer viruses and interruption or loss of valuable business data. Stored data might be improperly accessed due to a variety of events beyond our control, including, but not limited to, damage and interruption from power loss or natural disasters, computer system and network failures, loss of telecommunications services, physical and electronic loss of access to data and information, terrorist attacks, hackers, security breaches or other security incidents, and computer viruses or attacks. A failure of any third parties who maintain our information technology systems to provide adequate and timely support could adversely affect the operation of our information technology systems.

Hackers and data thieves are increasingly sophisticated and operate large-scale and complex attacks (including through the use of artificial intelligence), which may remain undetected until after they occur. In some cases, attempted attacks and intrusions are designed not to be detected and, in fact, may not be detected. Such attacks also may be further enhanced in frequency or effectiveness through threat actors' use of artificial intelligence. Computer hackers may attempt to penetrate our computer systems or those of our third-party vendors and, if successful, misappropriate our proprietary and confidential information including e-mails and other electronic communications. In addition, an employee, contractor, or other third party with whom we do business may attempt to obtain such information and may purposefully or inadvertently cause a breach involving such information. Any such compromise of our data security and access to, or public disclosure or loss of, confidential business or proprietary information could disrupt our operations, damage our reputation, provide our competitors with valuable information and subject us to additional costs, which could adversely affect our business.

The costs of mitigating cybersecurity risks are significant and are likely to increase in the future. These costs include, but are not limited to, retaining the services of cybersecurity providers; compliance costs arising out of existing and future cybersecurity, data protection and privacy laws and regulations; costs related to maintaining redundant networks, data backups and other damage-mitigation measures; and extra administrative costs to mitigate risk and deal with any system breaches.

We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability.

Our products and product candidates could cause adverse effects. These adverse effects may not be observed in clinical trials but may nonetheless occur in the future. If any of these adverse effects occur, they may render our product candidates ineffective or harmful in some patients, and our sales would suffer, materially adversely affecting our business, financial conditions and results of operations.

In addition, potential adverse effects caused by our product candidates, or products, could lead to product liability claims. Product liability claims might be brought against us by consumers, healthcare providers or others coming into contact with our products. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our product candidates for which we obtain marketing approval;
- impairment of our business reputation and exposure to adverse publicity;
- increased warnings on product labels;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenue; and
- the inability to successfully commercialize our product candidates for which we obtain marketing approval.

If product liability lawsuits are successfully brought against us, our insurance may be inadequate.

We have obtained liability insurance coverage for our clinical trials with limits that are customary for such trials. However, our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, in the future, we may be unable to maintain insurance coverage at a reasonable cost or in sufficient amounts to adequately protect us against losses due to liability. If and when we obtain marketing approval for any of our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain this product liability insurance on commercially reasonable terms. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial. A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

The product liability insurance we will need to obtain in connection with the commercial sales of our product candidates, if and when they receive regulatory approval, may be unavailable in meaningful amounts or at a reasonable cost. If we are the subject of a successful product liability claim that exceeds the limits of any insurance coverage we obtain, we would incur substantial charges that would adversely affect our earnings and require the commitment of capital resources that might otherwise be available for the development and commercial launch of our product programs.

If we are unable to obtain adequate insurance to protect our business and property against damage, our financial condition could be adversely affected in the event of uninsured or inadequately insured loss or damage. Our ability to effectively recruit and retain qualified officers and directors could also be adversely affected if we experience difficulty in obtaining adequate directors' and officers' liability insurance.

We may not be able to obtain insurance policies on terms affordable to us that would adequately insure our business and property against damage, loss or claims by third parties. To the extent our business or property suffers any damages, losses or claims by third parties, which are not covered, or adequately covered, by insurance, our financial condition may be materially adversely affected. If we are unable to obtain appropriate insurance, medical centers may be unwilling or unable to enter into site agreements to clinically test our candidate products.

We may be unable to maintain sufficient insurance as a public company to cover liability claims made against our officers and directors. If we are unable to adequately insure our officers and directors, we may not be able to retain or recruit qualified officers and directors to manage the Company.

We manage our business through a small number of senior executive officers. We depend on them even more than similarly situated companies.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our senior executive officers. The loss of the services of our management personnel, including without limitation, our Executive Chairman, Shai Novik, our Chief Executive Officer, Dr. Oren Hershkovitz, or our Chief Medical Officer, Dr. Einat Galamidi or the inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results.

Because of the specialized scientific nature of our business, we rely heavily on our ability to attract and retain qualified senior executive officers with scientific and technical experience. In particular, the loss of one or more of our senior executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We do not currently carry "key person" insurance on the lives of members of senior management. The competition for qualified personnel in the pharmaceutical field is intense. Due to this intense competition, we may be unable to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs relating to public company reporting obligations under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). and regulations regarding corporate governance practices. Our management and other personnel devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations result in considerable legal and financial compliance costs. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors (the "Board," or the "Board of Directors") or Board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' liability insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. The continuous process of strengthening our internal controls and complying with Section 404 is complicated and time-consuming. As our business continues to grow both domestically and internationally, our internal controls will become more complex and will require significantly more resources and attention to ensure our internal controls remain effective overall.

During the course of our review and testing of our internal controls, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our shares to fall.

Environmental, social and corporate governance ("ESG") issues, including those related to climate change and sustainability, may have an adverse effect on our business, financial condition and results of operations and damage our reputation.

In recent years, there has been an increasing focus from certain investors, customers, consumers, employees and other stakeholders concerning ESG matters, including climate change, energy and water use, plastic waste and other sustainability concerns. If our ESG practices fail to meet regulatory requirements or investor, customer, consumer, employee or other stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, Board of Directors and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency, our reputation, brand and employee retention may be negatively impacted, and our suppliers may be unwilling to continue to do business with us. Further, if we do not adapt to or comply with new regulations, or fail to meet investor, industry or stakeholder expectations and concerns regarding ESG issues, investors may reconsider their capital investment in our Company, we may become subject to penalties, and customers and consumers may choose to stop purchasing our products, if approved for commercialization, which could have a material adverse effect on our reputation, business or financial condition.

Risks Related to Our Reliance on Third Parties

We depend on third parties to conduct our clinical trials.

We currently rely, and for the foreseeable future, will continue to rely, on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories to oversee most of the operations of our clinical trials and to perform data collection and analysis. As a result, we may face additional delays outside of our control if these parties do not fulfill their obligations in a timely fashion or in accordance with regulatory requirements. If these third parties do not successfully carry out their contractual duties or obligations and meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our financial results and the commercial prospects for our product candidates or any other potential product candidates could be harmed, our costs could increase and our ability to obtain regulatory approval and commence product sales could be delayed.

We may rely on third party manufacturers to manufacture our product candidates for purposes of clinical trials and commercial quantities of our product candidates, if and when approved for marketing by the applicable regulatory authorities.

With respect to the production of the starting material required for future clinical trials, we may rely either on our own manufacturing capabilities or on third parties. We currently, and in the future will, rely upon blood banks and collection service facilities for the collection of starting material for the production of Allocetra™. We plan to initially rely upon hospitals, other health care providers, contract manufacturers and, potentially, collaboration partners, to manufacture commercial quantities of our product candidates, if and when approved for marketing by the applicable regulatory authorities. Although we have not yet engaged any contract manufacturers or other service providers, if and when we do, our contract manufacturers and service providers must complete technology transfer, process validation for the manufacturing process and demonstrate successful manufacturing of comparable product. If our contract manufacturers and service providers, and their respective facilities, as applicable, are not approved by EMA, or other applicable regulatory authorities, our commercial supply of the product candidate will be significantly delayed and may result in significant additional costs. If we need to identify additional finished product manufacturers, we would not be able to do so without significant delay and likely significant additional cost.

Our and our contract manufacturers' and other service providers' failure to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury or death, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers and service providers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. Our future contract manufacturers and service providers may not perform as agreed or may not remain in the contract manufacturing business. In the event of a natural disaster, business failure, strike or other difficulty, we may be unable to replace our manufacturing capacity or a third-party manufacturer or provider in a timely manner and the production of our product candidates would be interrupted, resulting in delays and additional costs. See also "Risk Factors—Risks Related to our Business, Industry and Regulatory Requirements—Our manufacturing processes are complex, delicate and susceptible to contamination, and involve biological intermediates that are subject to stringent regulations."

We intend to rely primarily on third parties to market and sell Allocetra™ and any other product candidate.

We have no sales or distribution capabilities. To the extent we rely on third parties to commercialize our products, if marketing approval is obtained, we may receive less revenue than if we commercialize such products ourselves. In addition, we would have less control over the sales efforts of any third parties involved in our commercialization efforts. In the event we are unable to collaborate with a third-party marketing and sales organization to commercialize our products, particularly for broader patient populations, our ability to generate revenue will be limited.

Although we may ultimately develop a marketing and sales force with technical expertise and supporting distribution capabilities in the longer term, we do not currently intend to do so; therefore, we will be unable to directly market our products, if any, in the near future. To promote any of our potential products through third parties, we will have to locate acceptable third parties for these functions and enter into agreements with them on acceptable terms, and we may not be able to do so. Any third-party arrangements we are able to enter into may result in lower revenues than we could achieve by directly marketing and selling our potential products. In addition, to the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, as well as the terms of our agreements with such third parties, which cannot be predicted in most cases at this time. As a result, we might not be able to market and sell our products in the United States or overseas, which would have a material adverse effect on us.

Risks Related to Our Intellectual Property

The failure to obtain or maintain patents, licensing agreements and other intellectual property could impact our ability to compete effectively.

To compete effectively, we need to develop and maintain a proprietary position with regard to our own technologies, intellectual property, licensing agreements, product candidates and business. Legal standards relating to the validity and scope of claims in the biotechnology and biopharmaceutical fields are still evolving. Therefore, the degree of future protection for our proprietary rights in our core technologies and any product candidates or products that might be developed using these technologies is also uncertain. The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- while the patents we own have been issued, pending patent applications we have filed may not result in issued patents or may take longer than we expect to result in issued patents;
- we may be subject to interference or reexamination proceedings;
- we may be subject to opposition proceedings in foreign countries;
- any patents that are issued may not provide meaningful protection for any significant period of time, if at all;
- we may not be able to develop additional proprietary technologies that are patentable;
- other companies may challenge and invalidate patents licensed or issued to us or our customers;
- other companies may independently develop similar or alternative technologies, or duplicate our technologies;
- other companies may design around technologies we have licensed or developed; and
- enforcement of patents is complex, uncertain and expensive, and our patents may be found invalid or enforceable.

We cannot be certain that patents will be issued as a result of any of our pending applications, and we cannot be certain that any of our issued patents, whether issued pursuant to our pending applications or licensed from third parties, will give us adequate protection from competing products. For example, issued patents may be circumvented or challenged, declared invalid or unenforceable, or narrowed in scope, and changes in the law may affect the utility of a pending patent application or issued patent. In addition, because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions or to file patent applications covering those inventions. If any of our composition of matter patents, or pending applications, was subject to a successful challenge or failed to issue, our business and competitive advantage could be significantly affected. Our current patents will expire or they may otherwise cease to provide meaningful competitive advantage, and we may be unable to adequately develop new technologies and obtain future patent protection to preserve our competitive advantage or avoid adverse effects on our business.

Although we expect to do so, we may not be able to submit a marketing application seeking approval of Allocetra™ prior to the applicable patents' expiration date, assuming all necessary patents are in fact issued. Moreover, we cannot be certain that we will be the first applicant to obtain FDA and/or EMA approval for any indication of our product candidates and we cannot be certain that we will be entitled to any other exclusivity with respect to the same. Such a diminution of our proprietary position could have a material adverse effect on our business, results of operation and financial condition.

Our ability to protect and enforce our patents does not guarantee that we will secure the right to commercialize our patents.

A patent is a limited monopoly right conferred upon its holder, and such holder's successors in title, in return for the making and disclosing of a new and non-obvious invention. This monopoly is of limited duration but, while in force, allows the patent holder to prevent others from making and/or using his/her invention without the patent holder's consent. While a patent gives the holder this right to exclude others, it is not a license to commercialize the invention, where other permissions may be required for permissible commercialization to occur. Further, the invention, even if patented itself, cannot be commercialized if it infringes the valid patent rights of another party.

Others may obtain issued patents that could require us to obtain licenses requiring the payment of significant fees or royalties in order to enable us to conduct our business. As to those patents that we may license, our rights would depend on maintaining our obligations under the applicable license agreement, and we may be unable to do so. The requirement to either obtain licenses or to maintain our obligations under license agreements, even if successful, could be costly for us and there is no guarantee such licenses will permit us to commercialize the underlying patents.

We may rely on trade secrets and proprietary know-how to protect our proprietary technology, which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We require our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the disclosure of confidential information to any other party. We also require our employees and consultants to disclose and assign to us their ideas, developments, discoveries and inventions. These agreements may not, however, provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our business and competitive position would be harmed.

We may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. As such, we may not be able to prevent third parties from duplicating our inventions, or from selling or importing products made using our inventions, in countries outside those for which we have legally obtained patent protection. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities, and could materially adversely affect our competitive advantage, business and results of operations. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

The biotechnology industry has been characterized by significant litigation and other proceedings regarding patents, patent applications, and other intellectual property rights.

The biotechnology industry has been characterized by extensive and frequent litigation regarding patents and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include:

(i) litigation or other proceedings we may initiate against third parties to enforce the patent rights or other intellectual property rights;

(ii) litigation or other proceedings we may initiate against third parties seeking to invalidate the patents held by such third-parties or to obtain a judgment that the technology does not infringe such third parties' patents;

(iii) litigation or other proceedings third parties may initiate against us seeking to invalidate the patents or to obtain a judgment that third-party technology or products do not infringe the patents; and

(iv) if competitors file patent applications claiming technology also claimed by, we may be forced to participate in interference or opposition proceedings to determine the priority of invention.

The costs of resolving any patent litigation, or other intellectual property proceeding, even if resolved in our favor, could be substantial. Such costs, or uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings, could materially adversely affect our competitive advantage, business and results of operations.

We cannot predict the scope and extent of patent protection for our product candidates because the patent positions of pharmaceutical products are complex and uncertain.

Any patents issued to us will not ensure the protection of our intellectual property for a number of reasons, including, without limitation, the following:

- any issued patents may not be broad or strong enough to prevent competition from other products including identical or similar products;
- if we are not awarded patents or if issued patents expire or are declared invalid or not infringed, there may be no protections against competitors attempting to make "biosimilars;"
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be other patents or pending patent applications existing in the patent landscape for our product candidates that will affect our freedom to operate;
- if our patents are challenged, a court could determine that they are not valid or enforceable;
- a court could determine that a competitor's technology or product does not infringe our patents;
- our patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations, or could be subject to compulsory licensing; and
- if we encounter delays in our development or clinical trials, the period of time during which we could market our products under patent protection would be reduced.

We may not be able to enforce our intellectual property rights throughout the world. This risk is exacerbated because we expect that our product candidates will be manufactured and used in a number of countries.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This risk is exacerbated for us because we expect our product candidates will be manufactured and used in a number of countries.

The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our other intellectual property rights. For example, several foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Certain countries may not provide the same or similar protection as that provided in the United States. Additionally, due to uncertainty in patent protection law, we have not filed applications in many countries where significant markets exist, including, without limitation, South American countries, Eurasian countries, African countries and Taiwan.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical and biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical and biotechnology industries involve both technological and legal complexity. Therefore, obtaining and enforcing related patents is costly, time-consuming and inherently uncertain. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have ruled on several patent cases in recent years, and could do so again in the future, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition, the USPTO has implemented patentability guidelines that may render the subject matter of a patent as non-patentable based on a lack of utility. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by applicable courts and legislatures in the countries in which we may pursue patent protection, including those of the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents and the interpretations of such laws could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may be unable to protect the intellectual property rights of the third parties from whom we license or may license certain of our intellectual property or with whom we have entered into other strategic relationships, which could have a material adverse effect on our business, results of operations and financial condition.

Certain of our intellectual property rights are and may in the future continue to be licensed from third parties, including universities and/or strategic partners. Such third parties may not protect the intellectual property rights that we license from them, and we may be unable to defend such intellectual property rights on our own (even if we contractually agree to manage, maintain and defend such rights) or we may have to undertake costly litigation to defend the intellectual property rights of such third parties. There can be no assurances that we will continue to have proprietary rights to any of the intellectual property that we license from such third parties or otherwise have the right to use through similar strategic relationships. Any loss or limitations on use with respect to such intellectual property licensed from third parties or otherwise obtained from third parties with whom we have entered into strategic relationships could have a material adverse effect on our business, results of operations and financial condition.

We may infringe on the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing, or increase the costs of commercializing, our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our products infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe. Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made, and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our products infringe. For example, pending applications may exist that provide support or can be amended to provide support for a claim that results in an issued patent that our product infringes.

Third parties may assert that we are employing their proprietary technology without authorization. If a court held that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our product candidates or products unless we obtained a license under the applicable patents, or until the patents expire. In addition to litigation proceedings which may be filed against us, we may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us.

We may be unable to adequately prevent disclosure and unauthorized use of trade secrets and other proprietary information by third parties.

Our ability to obtain and maintain patent protection and trade secret protection for our intellectual property and proprietary technologies, our products and their uses is important to our commercial success. We rely on a combination of patent, copyright, trademark and trade secret laws, non-disclosure and confidentiality agreements, licenses, assignment of inventions agreements and other restrictions on disclosure and use to protect our intellectual property rights.

We also rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements, to the extent they are in place and in effect, may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our product candidates or products or cause additional material adverse effects upon our competitive business position.

We cannot be certain that the steps that we have taken will prevent the misappropriation or other violation of our confidential information and other intellectual property, particularly in foreign countries in which laws may not protect our proprietary rights as fully as in the United States and other developed economies. Moreover, if we lose any key personnel, we may not be able to prevent these persons from impermissibly disclosing or using our technical knowledge or other trade secrets. If we are unable to maintain the security of our proprietary technology, this could materially adversely affect our competitive advantage, business and results of operations.

Under applicable U.S. and Israeli law, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

We generally enter into non-competition agreements with our employees and certain key consultants, or our employment and consulting agreements contain non-competition provisions. These agreements, to the extent they are in place and in effect, prohibit our employees and certain key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished.

Any lawsuits relating to infringement of intellectual property rights necessary to defend ourselves or enforce our rights will be costly and time consuming.

We may be required to initiate litigation to enforce our rights or defend our activities in response to the alleged infringement of a third party. In addition, we may be sued by others who hold intellectual property rights and who claim that their rights are infringed by our product candidates or any of our future products or product candidates. These lawsuits can be very time-consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally.

A third party may claim that we are using inventions claimed by their patents and may go to court to stop us from engaging in our normal operations and activities, such as research, development and the sale of any future products. Such lawsuits are expensive and would consume time and other resources. There is a risk that such a court will decide that we are infringing the third-party's patents and will order us to stop the activities claimed by the patents, redesign our products or processes to avoid infringement or obtain licenses, which may not be available on commercially reasonable terms. In addition, there is a risk that a court will order us to pay the other party damages for infringement.

Moreover, there is no guarantee that any prevailing patent owner would offer us a license so that we could continue to engage in activities claimed by the patent, or that such a license, if made available to us, could be acquired on commercially acceptable terms. In addition, third parties may, in the future, assert other intellectual property infringement claims against us with respect to our product candidates, technologies or other matters.

In addition, our patents and patent applications could face other challenges, such as interference proceedings, opposition proceedings and re-examination proceedings. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our patents and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time-consuming and expensive to defend and resolve and would divert our management's time and attention.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

Risks Related to the Ownership of Our Ordinary Shares

We do not know whether a market for our ordinary shares will be sustained or what the market price of our ordinary shares will be and as a result it may be difficult for you to sell your shares.

The trading price of our ordinary shares is likely to be volatile. The following factors, some of which are beyond our control, in addition to other risk factors described in this section, may have a significant impact on the market price of our ordinary shares:

- inability to obtain the approvals necessary to commence further clinical trials;
- unsatisfactory results of clinical trials;
- announcements of regulatory approval or the failure to obtain it, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;

- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our product candidates;
- any adverse changes to our relationship with manufacturers or suppliers;
- any product liability actions or intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical or biotechnology industries in general;
- achievement of expected product sales and profitability or our failure to meet expectations;
- our commencement of, or involvement in, litigation;
- any major changes in our Board, management or other key personnel;
- legislation in the United States, Europe and other foreign countries relating to the sale or pricing of pharmaceuticals;
- announcements by us of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments;
- expiration or terminations of licenses, research contracts or other collaboration agreements;
- public concern as to the safety of therapeutics we, our licensees or others develop;
- success of research and development projects;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares are covered by analysts;
- developments by our licensees, if any;
- future issuances of ordinary shares or other securities; and
- general political, economic and market conditions, including the war between Israel and Hamas.

These factors may materially and adversely affect the market price of our ordinary shares, which could result in substantial losses by our investors.

In addition, the stock market in general, and the Nasdaq Capital Market and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies like ours. Broad market and industry factors may negatively affect the market price of our ordinary shares, regardless of our actual operating performance. Further, a systemic decline in the financial markets and related factors beyond our control may cause our share price to decline rapidly and unexpectedly. The price volatility of our ordinary shares might be worse if the trading volume of our ordinary shares is low.

Moreover, the liquidity of our ordinary shares is limited. Among other factors, the number of ordinary shares that can be bought and sold at a given price, potential delays in the timing of executing transactions in our ordinary shares and a reduction in security analyst and media coverage of our company, if any, may result in lower prices for our ordinary shares and a larger spread between the bid and ask prices therefor. In addition, without a large float, our ordinary shares are less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our ordinary shares may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate its investment in our ordinary shares. Trading of a relatively small volume of our ordinary shares may have a greater impact on the trading price of our shares than would be the case if our public float were larger. We cannot predict the prices at which our ordinary shares will trade in the future.

We may be subject to securities litigation, which may be expensive and could divert management attention.

Companies that have experienced volatility and other negative fluctuations in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources from our business, which could materially harm our business, even if we were to successfully defend against such litigation. Any adverse determination in litigation could also subject us to significant liabilities.

Our principal shareholders, directors and officers currently own approximately 13.87% of our outstanding ordinary shares. They will therefore be able to exert significant influence over matters submitted to our shareholders for approval.

Our principal shareholders, directors and officers beneficially own approximately 13.87% of our outstanding ordinary shares. As a result, these shareholders, if they acted together, could significantly influence matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these shareholders may not always coincide with our interests or the interests of other shareholders.

Raising additional capital could result in dilution of our existing shareholders and may restrict our operations or require us to relinquish rights.

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

Our U.S. shareholders may suffer adverse tax consequences if we were to be characterized as a passive foreign investment company, or PFIC.

Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of the average value of our assets are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. There can be no assurance that we will not be classified as a PFIC in any year. If we were to be characterized as a PFIC for U.S. federal income tax purposes in any taxable year during which a U.S. Holder, as defined in "Taxation — United States Federal Income Tax Consequences," owns ordinary shares, such U.S. Holder could face adverse U.S. federal income tax consequences (regardless of whether we continue to be characterized as a PFIC in subsequent years), including having gains realized on the sale of our ordinary shares classified as ordinary income, rather than as capital gains, and subject to tax at the highest marginal ordinary income tax rate, a loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. Holders, having interest charges apply to distributions by us and the proceeds of share sales, and additional reporting requirements. Certain elections exist that may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares; however, we do not intend to provide the information necessary for U.S. Holders to make "qualified electing fund elections," or QEF elections, if we are classified as a PFIC, and, accordingly, such elections would not be available to U.S. Holders. See "Taxation—United States Federal Income Tax Consequences."

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our shares, our share price and trading volume could be negatively impacted.

The trading market for our ordinary shares may be influenced by research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts, and we cannot provide any assurance that analysts will cover us or, if they do, provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding our shares, or provide more favorable relative recommendations about our competitors, our share price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could negatively impact our share price or trading volume.

Because we do not intend to declare cash dividends on our ordinary shares in the foreseeable future, shareholders must rely on appreciation of the value of our ordinary shares for any return on their investment.

We have never declared or paid cash dividends on our ordinary shares. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Moreover, the Israeli Companies Law, 1999 (the "Companies Law"), imposes certain restrictions on our ability to declare and pay dividends. Payment of dividends may also be subject to Israeli withholding taxes. See Item 10.E "Additional Information—Taxation—Israeli Taxation Considerations" for more information. As a result, capital appreciation, if any, of our ordinary shares will be your sole source of gain for the foreseeable future. Consequently, in the foreseeable future, you will likely only experience a gain from your investment in our ordinary shares if the price of our ordinary shares increases beyond the price in which you originally acquired the ordinary shares.

We are a "foreign private issuer" under the Exchange Act, and our disclosure and reporting requirements are different than those of a U.S. domestic reporting company.

We are a "foreign private issuer" under the Exchange Act and the rules of the SEC promulgated thereunder. As a result, we are subject to the reporting requirements under the Exchange Act applicable to foreign private issuers. meaning that, among other things, we are required to file our Annual Report on Form 20-F with the SEC within four months following our fiscal year end. In addition, we are not subject to quarterly financial reporting, as would be the case for a U.S. domestic reporting company; therefore, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. We are additionally not required to comply with Regulation FD, which addresses certain restrictions on the selective disclosure of material non-public information. Also, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our ordinary shares. If we lose our status as a foreign private issuer, we will no longer be exempt from such rules and, among other things, will be required to file periodic reports and financial statements as if it were a company incorporated in the United States.

As a "foreign private issuer," we are permitted to follow certain home country corporate governance practices instead of otherwise applicable Nasdaq Capital Market requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. 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 Capital Market (the "Nasdaq Listing Rules") for U.S. issuers. For instance, we follow home country practice in Israel with regard to, among other things, director nomination procedures, quorum requirements, approval of compensation of officers and distribution of periodic reports. In addition, we follow our home country law instead of the Nasdaq Listing Rules that require that we obtain shareholder approval for certain dilutive events, such as the establishment or amendment of certain equity-based compensation plans, an issuance that will result in a change of control of the Company, the issuance of more than 20% of the equity 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 the Nasdaq Capital Market may provide less protection to you than what is accorded to investors under the Nasdaq Listing Rules applicable to domestic U.S. issuers. See "Item 16G — Corporate Governance."

Our ordinary shares are traded on more than one market, and this may result in price variations.

Our ordinary shares are traded on the Nasdaq Capital Market and the Tel Aviv Stock Exchange ("TASE"). Trading in our ordinary shares on these markets takes place in different currencies (U.S. dollars on Nasdaq and NIS on the TASE) and at different times, as a result of different time zones, trading days and public holidays in the United States and Israel. The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of our ordinary shares on the TASE could contribute to a decrease in the trading price of our ordinary shares on Nasdaq, and a decrease in the price of our ordinary shares on Nasdaq could likewise contribute to a decrease in the trading price of our ordinary shares on the TASE.

Risks Related to Israeli Law and Our Operations in Israel

Our headquarters and other significant operations are located in Israel and, therefore, our business and operations may be adversely affected by political, economic and military instability in Israel.

Our executive offices are located in Ness Ziona, Israel. In addition, our officers and several of our directors are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business and operations. 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 terrorist organizations active in the region. In recent years, Israel has been engaged in sporadic armed conflicts with Hamas, an Islamist terrorist group that controls the Gaza Strip, with Hezbollah, an Islamist terrorist group that controls large portions of southern Lebanon, and with Iranian-backed military forces in Syria, which have involved missile strikes, hostile infiltrations, terrorism against civilian targets in various parts of Israel, and recently abduction of soldiers and citizens.

On October 7, 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. In response, Israel's security cabinet declared war against Hamas and commenced a military campaign against Hamas and these terrorist organizations in parallel to their continued rocket and terror attacks. Subsequent to the commencement of the Hamas-Israel war, Hezbollah in Lebanon launched missile, rocket and shooting attacks against Israeli military sites, troops and Israeli towns in northern Israel; and the Houthis, a military organization based in Yemen, launched a series of attacks on global shipping routes in the Red Sea, as well as direct attacks on various parts of Israel. In response to these attacks, the Israeli army carried out a number of targeted strikes on sites belonging to Hezbollah and conducted ground operations in southern Lebanon. In April and October 2024, Iran launched direct attacks on Israel, involving hundreds of drones and ballistic missiles launched directly towards highly populated civilian areas and military bases. In November 2024, a ceasefire agreement was reached between Hezbollah in Lebanon and Israel; however, Hezbollah breached the ceasefire agreement in March 2025. In January 2025, a temporary ceasefire agreement was reached between Hamas in Gaza and Israel, but hostilities resumed in mid-March 2025. The continuation of the war has also led to a deterioration of certain indicators of Israel's economic standing, for instance, a downgrade in Israel's credit rating by rating agencies such as by Moody's, S&P Global, and Fitch. We cannot predict if and to what extent any ceasefire agreements will be reached or upheld.

In connection with the Israeli security cabinet's declaration of war against Hamas in October 2023 and possible hostilities with other organizations, several hundred thousand Israeli military reservists were drafted to perform immediate military service. While we have not been materially adversely impacted to date by any absences of our personnel, our operations could be disrupted by the absence of a significant number of our employees related to their, or their spouse's, military service or the absence for extended periods of one or more of our key employees for military service, which disruption may materially and adversely affect our business and results of operations.

Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government is currently committed to covering 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.

While we have not been materially impacted by the conditions in Israel since the war broke out in October 2023, hostilities continue to exist at varying levels of intensity, and the situation remains volatile, with the potential for escalation into a broader regional conflict involving additional terrorist organizations and possibly other countries, and we cannot predict how such conflicts will ultimately affect our business and operations or Israel's economy in general. These events could lead to increased costs, risks to employee safety, and challenges to business continuity, potentially resulting in financial losses.

The global perception of Israel and Israeli companies, influenced by actions by international judicial bodies, may lead to increased sanctions and other negative measures against Israel and Israeli companies. There is also a growing movement among countries, activists, and organizations to boycott Israeli goods and services or restrict doing business with Israel and Israeli companies. These restrictions may limit materially our ability to obtain raw materials from these countries or sell our products to companies in these countries (if approved). 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. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and product development, make it more difficult for us to do business and raise capital and adversely affect the share price of publicly traded companies having operations in Israel, such as us.

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, and has recently renewed its efforts to effect such changes. In response to the foregoing developments, certain individuals, organizations, and institutions, both within and outside of Israel, voiced concerns that such proposed changes, if adopted, may negatively impact the business environment in Israel. Such proposed changes may also lead to political instability or civil unrest. 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, growth prospects, and share price as well as our ability to raise additional funds.

Exchange rate fluctuations between the U.S. dollar, Euro and the NIS may negatively affect our earnings.

Our functional currency is the U.S. dollar because the U.S. dollar is the currency of the primary economic environment in which we operate and expect to continue to operate for the foreseeable future. Monetary assets and liabilities denominated in foreign currencies are translated into U.S. dollars using exchange rates in effect at the applicable balance sheet date. Because we incur expenses denominated in currencies other than the U.S. dollar, predominantly the NIS and Euro, fluctuations in exchange rates among these currencies may negatively impact our earnings, particularly if the NIS or Euro appreciates against the U.S. dollar. The average exchange rate for the year ended December 31, 2024 was $1.00 = Euro 3.7964 and $1.00 = NIS 3.647.

Enlivex Therapeutics R&D Ltd., our primary operating subsidiary, received Israeli government grants for certain of our research and development activities. The terms of those grants may require us, in addition to payment of royalties, to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. We may be required to pay penalties in addition to repayment of the grants.

The research and development efforts of our primary operating subsidiary, Enlivex Therapeutics R&D Ltd., a company organized under the laws of the State of Israel ("Enlivex R&D"), have been financed in part through royalty-bearing grants, in the aggregate amount of approximately $8.0 million, from the Israel Innovation Authority (the "IIA"), pursuant to the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Encouragement of Industrial Research and Development Law, 5744-1984) (the "Innovation Law"). As of December 31, 2024, Enlivex R&D had not paid any royalties to the IIA and had a contingent obligation to the IIA, including interest, of $9.8 million.

Under the Innovation Law as currently in effect, we are committed to pay royalties at a rate of 3% to 5% on our sales proceeds from any products or services based on know-how funded by the IIA research and development grants Enlivex R&D received (which rates may be increased under certain circumstances) up to the total amount of grants received (which may be increased under certain circumstances), linked to the U.S. dollar and bearing interest. Until October 25, 2023, the interest was calculated at a rate based on the last published 12-month LIBOR applicable to U.S. dollar deposits. On October 25, 2023, the IIA published a directive concerning changes in royalties to address the expiration of the LIBOR, according to which, (a) for IIA grants approved between January 1, 1999 and June 30, 2017 – the annual interest will be the interest in effect at the time of the grant approval; (b) for IIA grants approved between July 1, 2017 and December 31, 2023 – for the period prior to December 31, 2023, the interest shall be calculated based on the 12-month LIBOR applicable to U.S. dollar deposits, as published on the first trading day of each year or in an alternative publication of the Bank of Israel; and for periods as of January 1, 2024, the annual interest shall be calculated at a rate based on the 12-month secured overnight financing rate ("SOFR"), or at an alternative rate published by the Bank of Israel plus 0.71513%; and (c) for IIA grants approved on or following January 1, 2024, the annual interest shall be the higher of (i) the 12 months SOFR interest rate, plus 1%, and (ii) a fixed annual interest rate of 4%.

Regardless of any royalty payment, we are required to comply with the requirements of Innovation Law with respect to those past grants. The terms of such IIA grants and the Innovation Law restrict the transfer of IIA-funded know-how and rights related thereto, technology and products to a third party or the transfer of manufacturing or manufacturing rights of the same outside of Israel (except for the transfer of up to 10% of the manufacturing capacity in the aggregate which requires only a notice to the IIA), without the prior IIA approval. Therefore, if deemed IIA-funded, the discretionary approval of an IIA committee would be required for any such transfer to third parties outside of Israel, which could, if we receive such approvals, result in the payment of increased royalties (both increased royalty rates and increased royalties ceilings) in cases of transfer of manufacturing outside of Israel (up to three times the amount of the IIA grants received, depending on the manufacturing volume performed outside Israel, plus accrued interest) and/or payment of additional amounts to the IIA in cases of transfer of IIA-funded know-how outside of Israel (calculated according to a formula under the Innovation Law, which may be in the amount of up to six times the amount of the grants received (less paid royalties, if any, and depreciation, but no less than the total grants received), plus accrued interest).

These restrictions and requirements for payment may impair our ability to sell our IIA funded technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any such product or technology outside of Israel. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of Israel of IIA-funded know-how, technology or products (such as a merger or similar transaction) may be reduced by any amounts that we may be required to pay to the IIA.

Our obligations and limitations pursuant to the Innovation Law are not limited in time and may not be terminated by us at will and remain in force even after we have paid all required royalties. Such restrictions and payments could materially restrict or limit our ability to perform or outsource manufacturing outside of Israel or otherwise transfer or license our IIA-supported know-how, technology or products, which could materially affect our business, results of operations and financial position.

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

Provisions of Israeli law and our Amended and Restated Articles of Association could have the effect of delaying or preventing a change in control and may make it more difficult for a third-party to acquire us or our shareholders to elect different individuals to our Board of Directors, even if doing so would be considered to be beneficial by some of our shareholders, and may limit the price that investors may be willing to pay in the future for our ordinary shares. Among other things, 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 such types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date on which a merger proposal is filed by each merging company with the Israel Registrar of Companies and at least 30 days have passed from the date on which the shareholders of both merging companies have 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 positive responses from the holders of at least 95% of the issued share capital. Completion of the tender offer also requires the approval of a majority of the offerees that do not have a personal interest in the tender offer, unless, following consummation of the tender offer, the acquirer would hold at least 98% of the Company's outstanding shares. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition, unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights.

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

In addition, our Amended and Restated Articles of Association do not provide for cumulative voting in the election of directors, which limits the ability of minority shareholders to elect director candidates, and provide that director vacancies may be filled by our Board of Directors, which may prevent shareholders from being able to fill vacancies on our Board of Directors.

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

We are organized in Israel. All of our executive officers and the majority of our directors reside outside of the United States, and all of our assets are located outside of the United States. Therefore, a judgment obtained against us, or any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States. 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 or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on an alleged violation of U.S securities laws 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. Additionally, Israeli courts might not enforce judgments obtained in the United States against us or our non-U.S. directors and executive officers, which may make it difficult to collect on judgments rendered against us or our non-U.S. officers and directors.

Your rights, liabilities and responsibilities as a shareholder will be governed by Israeli law and will differ in some material respects from those under U.S. law.

Because we are an Israeli company, the rights and responsibilities of our shareholders are governed by our Amended and Restated Articles of Association and Israeli law, including the Companies Law. These rights, liabilities and responsibilities differ in some material respects from the rights, liabilities and responsibilities of shareholders in a U.S. corporation. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders and to refrain from abusing his, her or its power in the company, including, among other things, in voting at the general meeting of shareholders on certain matters. Israeli law provides that these duties are applicable to shareholder votes on, among other things, amendments to a company's articles of association, increases in a company's authorized share capital, mergers and interested party transactions requiring shareholder approval under Israeli law. In addition, a controlling shareholder of an Israeli company or a shareholder who is aware that it possesses the power to determine the outcome of a shareholders' vote or to appoint or prevent the appointment of a director or executive officer in the company or has other powers towards the company, has a duty of fairness towards the company. However, Israeli law does not define the substance of this duty of fairness. There is limited case law available to assist us in understanding the implications of these provisions that govern shareholders' actions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

ITEM 4. INFORMATION ON THE COMPANY

4.A. History and Development

We were originally incorporated on January 22, 2012 under the laws of the State of Israel as Bioblast Pharma Ltd. ("Bioblast"). On March 26, 2019, Bioblast and Enlivex R&D (formerly known as Enlivex Therapeutics Ltd.) consummated a merger transaction whereby Enlivex R&D merged with a wholly owned subsidiary of Bioblast, with Enlivex R&D as the surviving entity in the merger (the "Merger"). As a result of the Merger, Enlivex R&D became a wholly owned subsidiary of Bioblast. In connection with the consummation of the Merger, Bioblast changed its name from "Bioblast Pharma Ltd." to "Enlivex Therapeutics Ltd."

Our primary operating subsidiary, Enlivex R&D, was originally incorporated as Tolarex Ltd. in September 2005 under the laws of the State of Israel. In February 2010, Enlivex R&D changed its name to Enlivex Therapeutics Ltd., and upon consummation of the Merger, to Enlivex Therapeutics R&D Ltd. In June 2021, Enlivex Therapeutics RDO Ltd. was established in Israel as a wholly owned subsidiary. Our principal executive offices are located at 14 Einstein Street, Ness Ziona, Israel 7403618 and our telephone number is: +972 26208072. Our wholly owned U.S. subsidiary, Enlivex Therapeutics Inc., incorporated in Delaware, has been appointed our agent in the United States, and its registered address is 1811 Silverside Road, Wilmington, Delaware 19810. Our website address is https://www.enlivex.com. The information contained on, or that can be accessed through, our website is not part of this Annual Report on Form 20-F. We have included our website address herein solely as an inactive textual reference. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of this website is http://www.sec.gov.

Our capital expenditures for the three years ended December 31, 2024, 2023 and 2022 were insignificant. See "Operating and Financial Review and Prospects—Liquidity and Capital Resources."

4.B. Business Overview

Overview

The Company is a clinical-stage macrophage reprogramming immunotherapy company, developing Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state. Resetting non-homeostatic macrophages into their homeostatic state is critical for immune system rebalancing and resolution of debilitating and life-threatening conditions. Non-homeostatic macrophages contribute significantly to the severity of a given disease. By restoring macrophage homeostasis, Allocetra™ has the potential to provide a novel immunotherapeutic mechanism of action for debilitating and life-threatening clinical indications that are defined as "unmet medical needs," as a stand-alone therapy or in combination with leading therapeutic agents.

Macrophages are tissue-resident or infiltrating immune cells critical for innate immunity, normal tissue development, and repair of damaged tissue. Macrophages' function is a result of their original designation, their local micro-environment, and the type of metabolites, substances or pathogens to which they are exposed. When reprogrammed out of their homeostatic state, macrophages contribute to the pathophysiology of multiple inflammatory diseases, including osteoarthritis, sepsis and various inflammatory disorders.

We believe the Company's primary innovative immunotherapy, Allocetra™, represents a paradigm shift in macrophage reprogramming, moving from targeting a specific subset of macrophages or a specific pathway affecting macrophage activity, to a fundamental view of macrophage homeostasis. Restoring macrophage homeostasis may induce the immune system to rebalance itself to normal levels of operation, thereby promoting disease resolution.

The Company is focused on osteoarthritis as its main chronic inflammatory indication. Osteoarthritis is a degenerative joint disease, characterized by low-grade inflammation, that affects more than 32.5 million adults in the United States. Treatment of osteoarthritis represents a substantial unmet medical need, particularly non-invasive treatments, as current therapeutic options are largely limited to pain management, lifestyle modifications, and, ultimately, joint replacement surgery. The Company believes that negatively reprogrammed macrophages may be key contributors to disease severity in osteoarthritis and that the effective reprogramming of these negatively reprogrammed macrophages into their respective homeostatic states may facilitate disease resolution.

In 2024, the Company made significant progress in its osteoarthritis clinical program, with a primary focus on the moderate to severe knee osteoarthritis trial. This multi-center, multi-country, double-blinded, placebo-controlled Phase I/II trial aims to evaluate the efficacy and safety of Allocetra™ in patients with moderate to severe knee osteoarthritis. Following the completion of the Phase I safety run-in stage, the Company announced positive interim results, demonstrating statistically significant improvements in pain, functionality, and stiffness at both three- and six-months post-treatment. The double-blind, randomized, placebo-controlled Phase II stage, which is statistically powered to assess the efficacy of Allocetra™ injections into the knee at the highest dose of Allocetra™ used in the Phase I stage, is ongoing. In April 2024, the Company completed the recruitment of the Phase II stage. Additionally, the Company is conducting trials in end-stage knee osteoarthritis, basal thumb osteoarthritis, psoriatic arthritis, and temporomandibular joint osteoarthritis. All planned and expected timelines for execution of clinical trials are subject to certain risks and uncertainties. For further discussion of risks and uncertainties related to our clinical trials, see Item 3.D. “Risk Factors” above.

During 2024, the Company also continued the development of its sepsis clinical program. In April 2024, the Company announced the 28-day topline data from the placebo-controlled, randomized, dose-finding, multi-center Phase II trial evaluating Allocetra™ in patients with pneumonia-associated sepsis, which was later expanded to include patients with sepsis resulting from biliary, urinary tract, or peritoneal infections. The 28-day topline data stand-alone analysis demonstrated substantial reductions in sequential organ failure assessment (“SOFA”) scores and a 65% reduction in overall mortality compared to expected mortality rates based on recently completed sizable clinical trials, particularly in patients with urinary tract infection (“UTI”)-related sepsis. The 12-month follow-up analysis demonstrated a continued favorable safety profile, as observed in the topline data, with no additional findings in the high-risk UTI-related sepsis group, as previously demonstrated in the 28-day topline data. We are continuing to close down all active sites and complete all required operations as part of the trial’s finalization.

In light of market conditions, the Company’s limited cash availability and the substantial budget required for advancing to a follow-up clinical trial in patients with sepsis, the Company plans to seek potential external collaboration or out-licensing opportunities for the continued clinical development of Allocetra™ for use in patients with sepsis, instead of pursuing internal development.

Osteoarthritis Clinical Program

Since our inception, due to its inherent properties, we have considered Allocetra™ as an innovative, highly differentiated modality for immune resolution across inflammatory and auto-immune indications. In September 2023, we initiated a clinical program in osteoarthritis, a degenerative disease characterized by low-grade inflammation that represents a substantial unmet medical need.

The pathogenesis of osteoarthritis affects an entire joint, including cartilage, synovial tissue, subchondral bone, and the joint capsule, and additionally results in inflammation of the synovium. Low-grade synovial inflammation has been observed in most osteoarthritis patients at both early and late stages of the disease. Inflammatory factors and mediators play a crucial role in the breakdown of the cartilage extracellular matrix (ECM) and cartilage damage. Osteoarthritis synovium contains elevated levels of immune cells, with activated macrophages being predominant. Pro-inflammatory macrophages release a broad spectrum of inflammatory and immune mediators into the synovial cavity, contributing to chronic inflammatory conditions, cartilage loss, and bone alteration. As pro-inflammatory macrophages play a crucial role in the initiation of osteoarthritis immunopathogenesis and low-grade chronic inflammation, reprogramming them into pre-resolution macrophages is considered an emerging target for osteoarthritis treatment. We believe that Allocetra™, which targets macrophages and macrophage-associated inflammatory pathways, may be a promising therapeutic strategy in the treatment of osteoarthritis.

The initiation of our osteoarthritis clinical program followed preclinical evidence demonstrating Allocetra's™ potential mechanism of action in resolving chronic low-grade inflammation in joints affected by osteoarthritis. This was further supported by observed recovery in a case study involving a 70-year-old patient with Gorham-Stout syndrome, a rare disease characterized by destruction of osseous matrix and proliferation of vascular structures. The patient, who had experienced complete destruction and absorption of the shoulder joint, showed substantial improvement following five intra-articular Allocetra™ injections, with maintained improvement documented at a two-year follow-up.

Moderate to Severe Knee Osteoarthritis

In January 2024, following receipt of the approval of the IMOH, we initiated a Company-sponsored multi-center, multi-country, double-blinded, placebo-controlled and statistically powered Phase I/II trial to evaluate efficacy as well as safety of Allocetra™ in patients with moderate to severe knee osteoarthritis and potentially allow the Company to design and initiate a clinical registrational trial upon its completion. This Phase I/II clinical trial is expected to enroll up to 160 patients and consists of two stages. The first stage, which we successfully completed, was a Phase I safety run-in, open-label dose escalation phase to characterize the safety and tolerability of Allocetra™ injections to the target knee in order to identify the dose and injection regimen for the subsequent Phase II stage. The Phase II stage is a double-blind, randomized, placebo-controlled, multi-center trial. In addition to evaluating safety, the trial's key efficacy endpoints will evaluate joint pain and joint function compared to placebo at three-, six- and 12-months post-treatment. The study design includes an interim statistical evaluation, conducted by an independent third party and blinded to the Company, to assess the potential value of enrolling up to 50 additional patients beyond the original randomized sample size of 130 and its marginal impact on the p-value of the statistical estimation for the total group and/or specific sub-group. In addition, the study incorporates an independent DSMB that reviews the safety data at three predefined time points.

In September 2024, we announced the recommendation by the independent DSMB to proceed with the randomized Phase II stage at the highest tested dose, as well as the Danish Medicines Agency's authorization to initiate this next trial stage.

In December 2024 and March 2025, we announced positive interim 3-month and 6-month efficacy data for the first 12 patients treated in the Phase I stage, demonstrating marked statistically significant improvements in all key efficacy endpoints. The 3-month and 6-month efficacy data included a 50% and 47% average pain reduction, respectively, as measured by the Numeric Rating Scale (NRS) pain screening tool, and 42% and 46% improvements in functionality, respectively, and 37% and 40% improvements in stiffness, respectively, in each case compared to baseline. The reported reduction in pain measured by the NRS was consistent with data from the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire, a widely used, standardized tool for evaluating osteoarthritis of the knee and hip, assessing pain, stiffness, and physical function. The 3-month and 6-month efficacy data showed a 52% and 51% reduction in WOMAC pain, respectively. At both intervals, 83% of the patients were considered responders to treatment (Fig 1). No serious adverse events were reported, although some patients experienced mild, transient discomfort or swelling in the knee following injection.

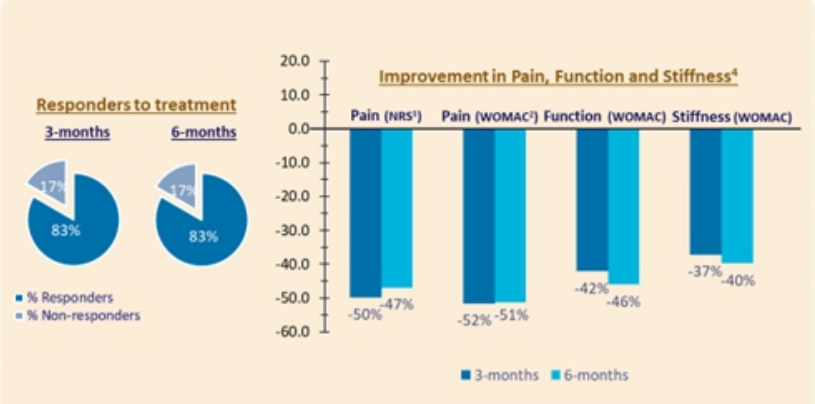

Figure 1

In April 2025, we announced the completion of the recruitment of all patients for the Phase II stage of the study. Overall, 133 patients were randomized and treated in the Phase II stage. We are currently targeting a three-month topline readout by August 2025 and a six-month topline readout by November 2025 for the Phase II stage of the trial.

End Stage Knee Osteoarthritis

During the third quarter of 2023, we announced the dosing of the first patient in a Phase I/II investigator-initiated clinical trial of Allocetra™ in patients with end-stage knee osteoarthritis who had been indicated for knee replacement surgery. In this study, patients with end-stage knee osteoarthritis were offered a single Allocetra™ injection to the knee as a potential "last resort" alternative for pain resolution and knee functionality in lieu of knee-replacement surgery.

In June 2024, we announced positive interim 3-month data for the trial, which showed a significant reduction in pain and a favorable safety profile. A total of nine patients have been enrolled and treated with a single Allocetra™ injection to the knee and evaluated for at least three months following treatment. Patients reported pain using a scale of zero (0, representing no pain) to ten (10, representing maximum pain). At the three-month follow up, a substantial reduction (64%) in average reported pain was observed compared to baseline, with 89% (8/9) of treated patients reporting an improvement in their knee pain compared to their baseline pain prior to treatment, and 33% (3/9) of the patients reporting complete pain relief from an average pain level of 9 to a pain level of 0. During the three-month period post injection of Allocetra™, only a single patient (1/9, 11%) decided to move forward with knee-replacement surgery, while 89% (8/9) of the patients decided not to proceed with such surgery (Fig 2). In all cases, dosing was successfully completed, and no severe related adverse events were reported following treatment.

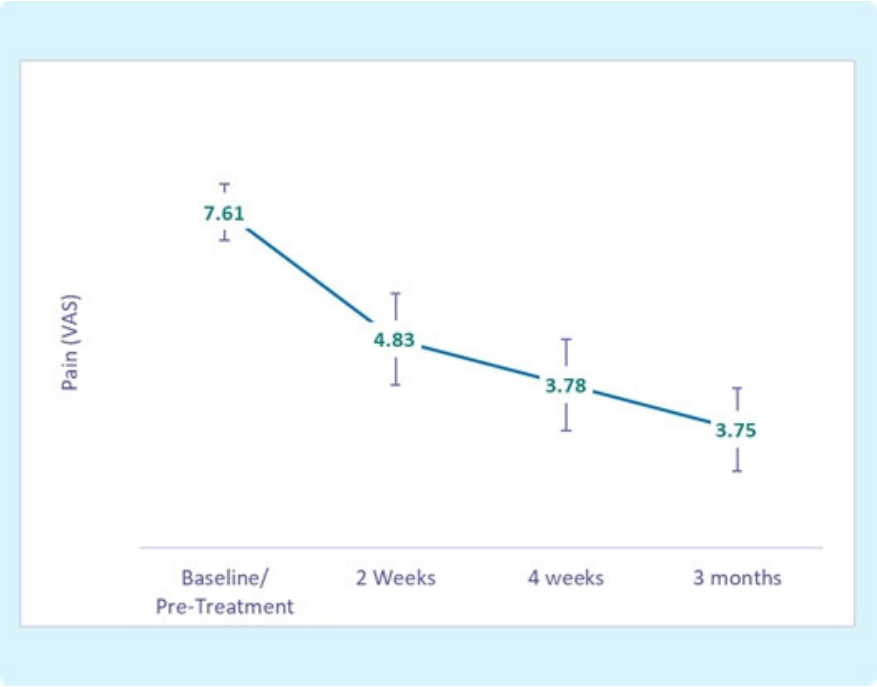

Figure 2

Recruitment to the study was completed and long-term follow up is ongoing. The study enrolled a total of 18 patients who were treated with a single injection of Allocetra™ to the afflicted knee. Patients are assessed for safety following dosing, and pain and function responses to treatment up to 12 months following injection.

Basal Thumb Osteoarthritis

In June 2024, following approval by the IMOH, we announced the dosing of the first patient in an investigator-initiated, randomized, placebo-controlled Phase I/II trial evaluating the efficacy and safety of Allocetra™ following injection into patients with basal thumb joint (first carpometacarpal (CMC) joint) osteoarthritis, for which conventional therapies have failed. This Phase I/II investigator-initiated, randomized, placebo-controlled trial plans to recruit up to 46 patients and is composed of two stages. The Phase I stage is a safety run-in, open-label dose escalation phase to characterize the safety and tolerability of Allocetra™ injection to patients with osteoarthritis of the first basal thumb joint (first CMC joint) of the target thumb who have failed conventional therapies, to identify the dose for the randomized stage. The Phase II stage is a planned double-blind, randomized, placebo-controlled stage, which is expected to be initiated following the completion of the safety run-in stage and selection of the safe and tolerable dose. Up to 40 patients will be randomized in a 1:1 ratio for treatment with either Allocetra™ at the selected dose or placebo. The primary safety endpoint will measure the frequency and severity of adverse events and serious adverse events, and the efficacy endpoints will include assessments of change from baseline in pain and function for up to 12 months. We are currently targeting to receive the three-month and six-month topline readouts for the Phase I stage of the trial by June 2025 and for the Phase II stage of the trial during the second half of 2025.

Psoriatic Osteoarthritis

In July 2024, we announced that the IMOH had authorized the initiation of a Company-sponsored Phase I clinical trial to evaluate the safety and tolerability of Allocetra™ following injection into an affected joint in patients with psoriatic arthritis. In November 2024, we announced the completion of the dosing and initial follow-up period for the first patient in this Phase I clinical trial, and no safety concerns were recorded. The trial currently plans to recruit six patients who have insufficiently responded to conventional therapies for psoriatic arthritis. The primary safety endpoint will measure the frequency and severity of adverse events and serious adverse events, and secondary endpoints will include assessments of change from baseline in pain and other parameters of disease activity for up to 12 months following administration of Allocetra™.

Temporomandibular Joint Osteoarthritis

In December 2024, the IMOH authorized the initiation of an investigator-initiated Phase I trial to evaluate the safety, tolerability and initial efficacy of Allocetra™ for injection into the temporomandibular joint ("TMJ") in patients suffering from TMJ osteoarthritis, which will be conducted by the Rheumatology Unit at Sheba Medical Center in collaboration with the Department of Oral and Maxillofacial Surgery. The Phase I trial aims to recruit six patients who have shown insufficient response to conventional treatments for TMJ osteoarthritis. The primary safety endpoint will measure the frequency and severity of adverse events and serious adverse events, and efficacy endpoints will assess changes from baseline in TMJ pain, joint functionality, and other disease parameters for up to 12 months following administration of Allocetra™. In April 2025, we announced that the dosing of the first patient was completed.

Sepsis Clinical Program

Sepsis is a highly heterogeneous syndrome that is caused by an unbalanced immune host response to an infection. Sepsis was not clinically defined until the early 1990s when a group of key opinion leaders released the first consensus definition of sepsis. Sepsis has been defined as a systemic inflammatory response syndrome ("SIRS") caused by an infection; and increasing severities have been designated as 'severe sepsis' (referring to sepsis and organ dysfunction) and 'septic shock' (referring to sepsis and refractory hypotension). In the most recent 'Sepsis-3' consensus definition, sepsis is defined as a life-threatening organ dysfunction that is caused by a dysregulated host response to infection, and the term "severe sepsis" has been removed. Notably, while infection is the triggering event in this definition of sepsis, the aberrant immune response often remains after successful treatment of the infection. This immune response is evidenced by a cytokine storm, a severe immune reaction in which the body releases too many cytokines into the blood too quickly, driving the severity of the clinical condition of sepsis patients. Sepsis imposes a substantial global burden in terms of morbidity and mortality.

Nearly all patients with severe sepsis require treatment in an intensive care unit. Sepsis, which has been identified by the World Health Organization as a global health priority, has no proven pharmacologic treatment other than appropriate antibiotic agents, fluids, and vasopressors. According to the CDC, at least 1.7 million adults in the United States develop sepsis each year, with approximately 270,000 dying of the disease. Among all sepsis cases, up to an estimated 31% are urosepsis, representing up to 2.8-9.8 million cases, and up to 1.6 million deaths annually worldwide (G. Bonkat et. al; 2018). Various studies estimate that sepsis is present in 30% to 50% of hospitalizations that culminate in death (Rhee et al; 2019).

Previous attempts to find a therapy for sepsis failed partially due to the parallel and complex course of biological activities that occur within a sepsis patient. For many years, a disproportionate inflammatory response to invasive infection was considered to be central to the pathogenesis of sepsis, but it is now clear that the host response is disturbed in a much more complex way, involving both sustained excessive inflammation and immune suppression, and a failure to return to normal homeostasis, which may lead to organ damage, multiple organ failure and mortality. If the immune system could be rebalanced, we believe that many of the negative outcomes, specifically organ damage and failure, could be prevented, which could significantly increase a patient's chance of survival with reduced morbidity.

Allocetra™ for the Treatment of Organ Dysfunction and Failure Associated with Sepsis

In late 2019, the Company completed its Phase Ib clinical trial of Allocetra™ in patients with severe sepsis. The aim of the Phase Ib clinical trial was to determine the safety and efficacy profile and tolerability of Allocetra™, in subjects admitted to the emergency room with sepsis. Allocetra™ ($140x10^6$ cells/kg) was administered in either a single dose to 6 patients at day 1 or in two doses to 4 additional patients at days 1 and 3, to patients admitted to the emergency room with sepsis. Patients were followed for 28 days. The study subjects were also compared to historical controls hospitalized in the intensive care unit ("ICU"), matched by age, gender, SOFA score, and infection source.

In March 2020, the Company announced the final safety and efficacy data from the Company's completed Phase Ib clinical trial. The final analysis compared the clinical data of 10 patients admitted to the ICU with sepsis who were administered Allocetra™ upon their admission, with 37 patients who were matched controls (matched by age, gender, SOFA score, and infection source) who received only the standard of care treatment at the same hospital during 2014-2019 but did not receive Allocetra™. The clinical trial was conducted at Hadassah Medical Center, which is one of the largest and most prestigious hospitals in Israel. The Acute Physiology and Chronic Health Evaluation (APACHEII) score of the Allocetra™-treated group was 12.9, and the corresponding probability of mortality of at least one patient in that group was predicted at 85% based on the hospital's ICU staff's clinical assessment of each patient's overall condition at admission. However, none (0%) of the Allocetra™-treated patients died during the 28-day study period, as compared to 27% 28-day mortality in the matched controls group. Each of the 10 Allocetra™-treated patients had between 2 to 5 dysfunctional organ systems upon admission to the ICU. All (100%) of the Allocetra™-treated patients had rapid and complete recovery from their septic conditions and of any organ dysfunction that was present upon admission to the ICU. Despite the similarity of SOFA scores at entry between the Allocetra™-treated patients and the matched controls group (average of 3.4 versus 3.47), not a single patient treated with Allocetra™ had any increase in organ-failure state post administration of Allocetra™, while the majority of the patients in the matched controls group had an increase in organ-failure state. The average worsening in organ-failure state of patients in the matched controls group was approximately 100% compared with their ICU hospitalization state vs zero (0%) percent worsening in organ-failure state of Allocetra™-treated patients post administration of Allocetra™ ($p< <0.0001$). The ICU length-of-stay for all Allocetra™-treated patients was significantly shorter than those patients who received only the standard of care, with an average of 4.7 days compared to 11.11 in the matched controls group, a 64% reduction ($p<0.0001$). The slowest ICU discharge of a patient treated with Allocetra™ was after 8 days, while approximately 50% of the matched controls group were still at the ICU after 28 days. Allocetra™ was shown to be safe and tolerable, with no serious unexpected severe adverse reactions and no serious adverse events.

Figures 2A - B present our Phase Ib trial results for evaluating Allocetra™ in patients with sepsis.

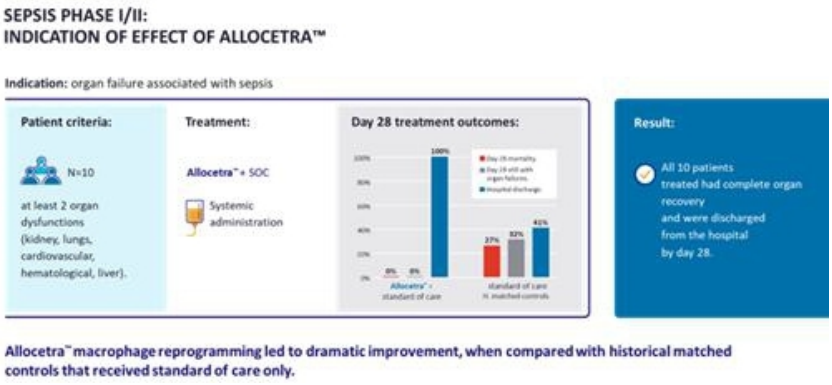

Figure 2A

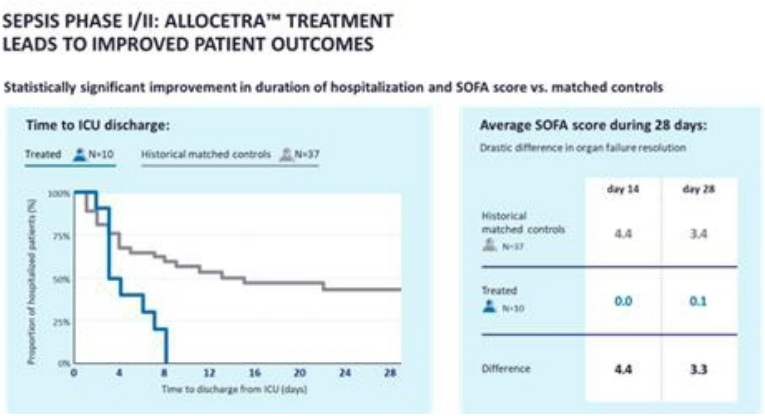

Figure 2B

In 2021, we initiated a placebo-controlled, randomized, dose-finding, multi-center, Phase II trial evaluating liquid Allocetra in patients with pneumonia-associated sepsis. During 2022, the Company amended the protocol of this clinical trial to treat newly recruited patients with frozen formulation Allocetra™ and expand the study population to include patients whose septic condition stems from biliary, urinary tract or peritoneal infections. An additional amendment to the study protocol was filed in the second quarter of 2023 to include an increase in the patients' SOFA score range, effectively allowing recruitment of patients with higher levels of sepsis severity, and a change to two cohorts (treatment and placebo) in lieu of the four-cohort structure previously contemplated. The first patient was dosed under the amended protocol during the second quarter of 2023 and in December 2023, the Company completed enrollment of all 120 patients in the trial.

Figure 2C presents the details of the Phase II clinical trial's design.

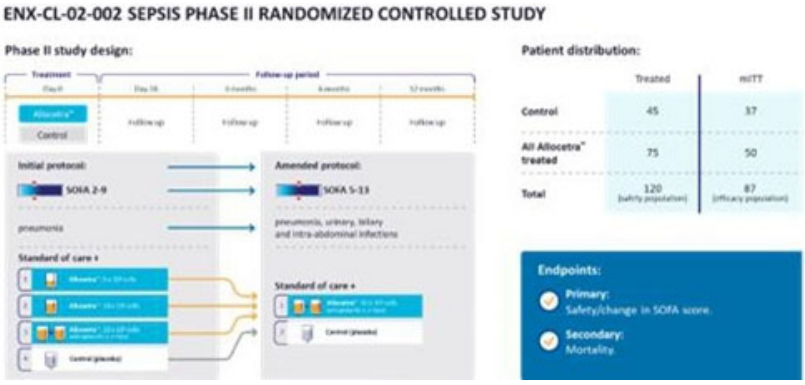

Figure 2C

In April 2024, we announced the 28-day topline data from the Phase II trial evaluating Allocetra™ in patients with sepsis. Stand-alone analysis of the Allocetra™-treated patients, of which 78% had septic shock and 58% had invasive ventilation at screening, demonstrated substantial reductions in SOFA scores and 65% reduction in overall mortality rate as compared with expected mortality based on real-world data and recent clinical sizeable studies in sepsis. By day 28, the analysis showed 90% reductions of SOFA scores for sepsis patients whose infection source was urinary tract, 68% for patients whose infection source was community-acquired pneumonia, and 36% for patients whose infection source was an internal abdominal infection. Relative analysis demonstrates a potential indication of effect of Allocetra™ as compared with placebo, in high-risk severe sepsis patient population, originating from UTIs. Up to an estimated 31% of sepsis cases start as UTIs, representing up to 9.8 million cases and up to 1.6 million deaths annually worldwide (G. Bonkat et. al. 2018), which represents a substantial potential market opportunity for Allocetra™. The 12-month follow-up data analysis demonstrated a long-term favorable safety profile of Allocetra™, with no additional insights from an efficacy perspective.

[2] Analysis of modified intent-to-treat (mITT) population for all patients who were randomized, received the high dose of Allocetra™ or placebo, had a screening total SOFA score >= 5 points above pre-admission total SOFA score, had at least one post-baseline total SOFA score, and determined as eligible by an adjudication committee.

Figures 2D - F provide a more detailed presentation of the Allocetra™ Phase II 28 days topline data results.

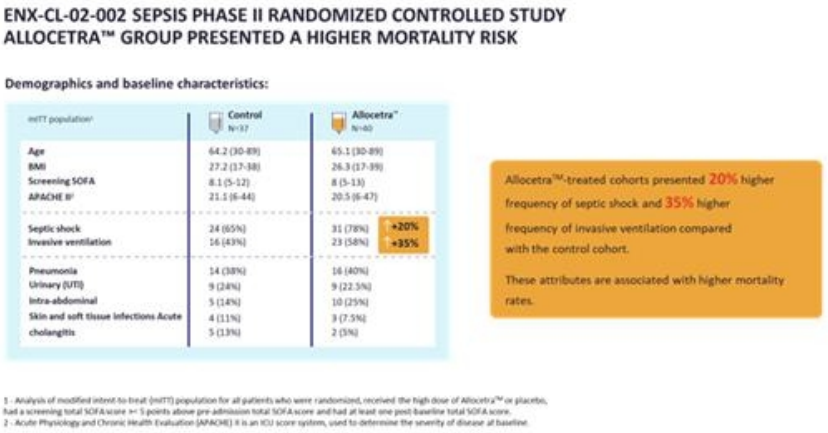

Figure 2D

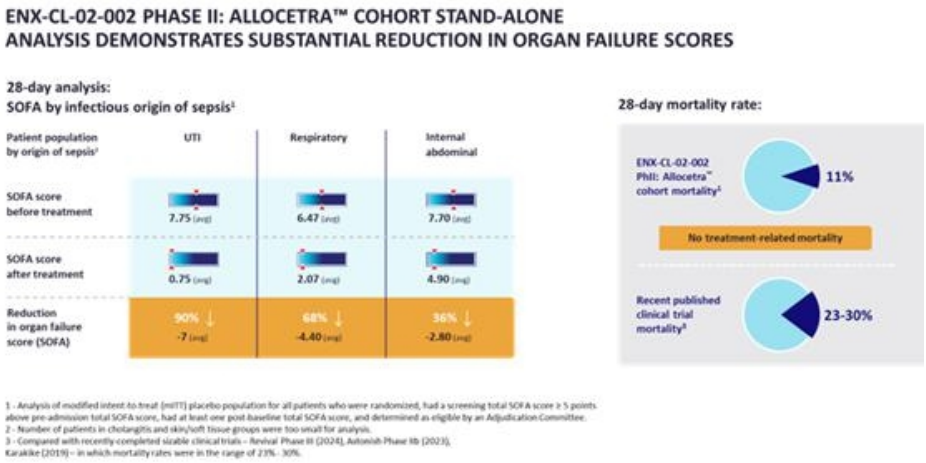

Figure 2E

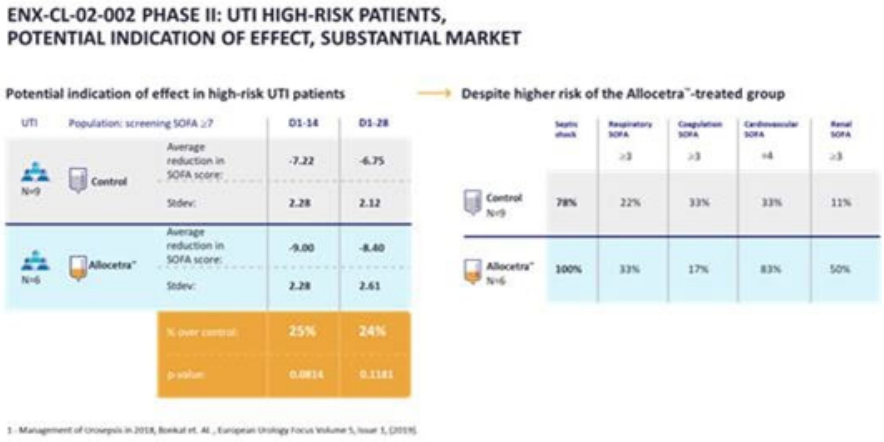

Figure 2F

The study was designed for patients to be randomized with equal degree of SOFA scores across treatment and placebo groups. The randomization resulted in the Allocetra™-treated cohorts having 20% higher frequency of septic shock and 35% higher frequency of invasive ventilation prior to treatment, as compared with the control group. Both of these patient attributes are associated with a significantly higher degree of difficulty of treatment and higher mortality rates. These imbalances made it challenging to deduce the relative effect in other patient subgroups.

Figure 2G provides further detail on the imbalances between the control and Allocetra™-treated cohorts.

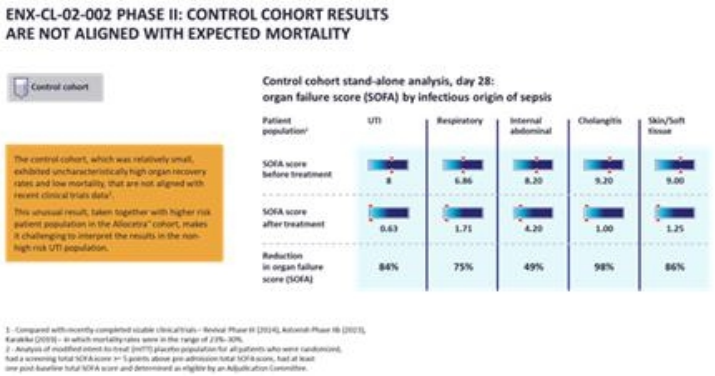

Figure 2G

Finally, stand-alone and placebo-compared analysis across all sepsis patient subgroups and risk categories demonstrated acceptable safety and tolerability profile of Allocetra™ IV infusions, as set forth in more detail in Figure 2H.

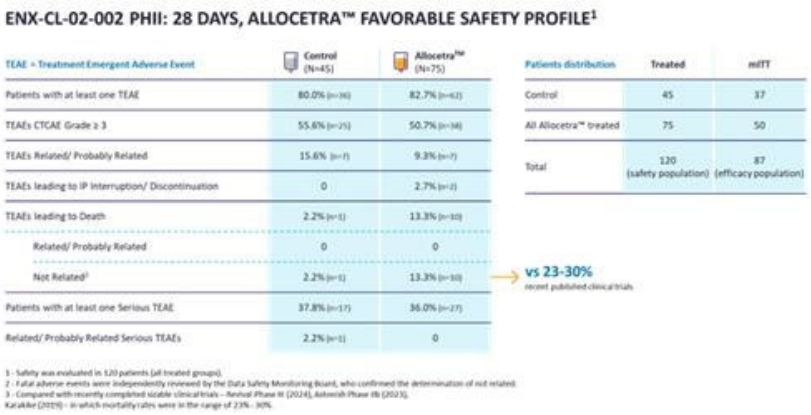

Figure 2H

The 12-month follow-up analysis demonstrated a continued favorable safety profile, as observed in the topline data, with no additional findings in the high-risk UTI-related sepsis group, as previously demonstrated in the 28-day topline data. We are continuing to close down all active sites and complete all required operations as part of the trial's finalization. In light of market conditions, the Company's limited cash availability and the substantial budget required for advancing to a follow-up clinical trial in patients with sepsis, the Company plans to seek potential external collaboration or out-licensing opportunities for the continued clinical development of Allocetra™ for use in patients with sepsis, instead of pursuing internal development.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology, intense competition and a highly uncertain, costly and lengthy research and development process. Adequate protection of intellectual property, successful product development, adequate funding and retention of skilled, experienced and professional personnel are among the many factors critical to success in these industries.

We believe that our product candidate offers key potential advantages over other drugs and therapies currently in use or in development that could enable our product candidate, if approved for the intended indications, to capture meaningful market share.

See "Risk Factors—Risks Related to Our Business, Industry and Regulatory Requirements—It is possible that none of our product candidates will achieve commercial success in a timely and cost-effective manner, or ever" and "Risk Factors—Risks Related to Our Business, Industry and Regulatory Requirements—Our market is subject to intense competition. If we are unable to compete effectively, Allocetra™ or any other product candidate that we may develop may be rendered uncompetitive or obsolete."

License Agreements

Tolaren Ltd.

In April 2008, Tolaren Ltd., which we refer to as Tolaren, granted to us an exclusive, irrevocable, worldwide, royalty free and sublicensable license to research, develop, commercialize, manufacture, market, sell, distribute and otherwise use and exploit a certain patent, patent rights and pending patent applications relating to the method for using apoptotic cells as a treatment for various autoimmune and inflammatory disorders and the production processes with respect to the same. The license further stipulates that all intellectual property rights, including any inventions, developments, discoveries, results, products data, information and know-how developed by the Company based on the licensed intellectual property rights, belong solely and exclusively to the Company and, to the extent such intellectual property rights are registrable, they may be registered in the name of the Company. We have used and continue to use such licensed technology to develop and produce Allocetra™. Pursuant to the license, we have agreed to manage, maintain and defend the licensed patents, including managing the registration of such patents in different countries. The license expires upon the expiration of the licensed patent; however, upon such expiration, we will have a fully paid-up, nonexclusive, unlimited, worldwide, sublicensable license to the technology developed on the basis of the patent and related patent rights and all inventions, know-how and other intellectual property owned or licensed by us and covered by the agreement or related thereto. The license is terminable by the Company upon 30-days prior written notice or by Tolaren if the Company ceases operations for a period of more than 360 days. Otherwise, the license for each of the patents endures until the expiration of such patent, and the license for any other licensed technology survives indefinitely.

Approximately 97% of the issued and outstanding share capital of Toleran is held by Hadasit Bio-Holdings Ltd., which was formerly a major shareholder.

Hadasit Medical Research Services and Development Ltd. and Yissum Research and Development Company Ltd.

In March 2006, the institutes jointly granted us an exclusive, worldwide, royalty free and sublicensable license to research, develop, commercialize, manufacture, market, sell, distribute and otherwise use and exploit a certain patent and patent rights relating to the therapeutic use of dead or dying cells, including apoptotic or necrotic cells, as well as any associated materials, methods or technology. The license further stipulates that all intellectual property rights, including any inventions, developments, discoveries, results, products data, information and know-how developed by the Company based on the licensed intellectual rights, belong solely and exclusively to the Company and, to the extent such intellectual property rights are registrable, they may be registered in the name of the Company. Pursuant to the license, we agreed to manage, maintain and defend the licensed patents, including managing the registration of such patents in different countries. The license expires upon the expiration of the licensed patent; however, upon such expiration, we will have a fully paid-up, nonexclusive, unlimited, worldwide, sublicensable license to the technology developed on the basis of the patent and related patent rights and all inventions, know-how and other intellectual property owned or licensed by us and covered by the agreement or related thereto. In addition to certain standard termination provisions relating to the financial condition of each party, we may terminate the license upon 30-days' prior written notice, and the institutes may terminate the license if we cease our operations for more than 120 days or if the institutes determine, in their reasonable discretion, that we have ceased making reasonable efforts to commercialize the licensed technology.

Hadasit Medical Research Services and Development Ltd. is the technology transfer office of Hadassah Hospital in Jerusalem, where Prof. Dror Mevorach, our former Chief Science & Medical Officer and currently a scientific advisor and consultant to the Company, is currently the Director of the Rheumatology Research Centre.

Intellectual Property and Patents and Proprietary Rights

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know-how are important to our business. As of March 16, 2025, we owned or in-licensed issued patents and pending patent applications in various jurisdictions worldwide, including 15 issued patents (with terms ranging from 2025 to 2038) and four pending patent applications in the United States; six issued patents (with terms ranging from 2026 to 2036) and three pending applications in Israel; four issued patents (with terms ranging from 2026 to 2036) and four pending patent applications with the European Patent Office (EPO); and one international patent application filed with the World Intellectual Property Organization under the PCT. Additionally, patents have been issued and/or patent applications are pending in Australia, Canada, China, Hong Kong, and Korea. We have sought patent protection for certain methods of producing and using autologous and allogeneic Allocetra. We also intend to seek patent protection for our discovery programs, and any other inventions to which we have rights, where available and when appropriate.

Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business.

Our commercial success will substantially depend on obtaining and maintaining patent protection and trade secret protection for our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We believe that our patents do, and filed patent applications will, provide broad and comprehensive coverage for the use of Allocetra™ as a treatment for our key target clinical indications. However, the patent positions of biotechnology companies, such as ourselves, are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position, if any, for the technology will depend on our success in obtaining effective claims and enforcing those claims once granted.

There is no certainty that any of our pending patent applications will result in the issuance of any patents. Our issued patents and those that may be issued in the future, could be challenged, narrowed, circumvented or found to be invalid or unenforceable, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, our competitors may independently develop similar technologies or duplicate any technology developed by us, and the rights granted under any issued or future patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of such patent. For further discussion of risks and uncertainties related to our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property” above.

Trade Secrets

In addition to owned and licensed patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary processes, in part, by confidentiality and intellectual property ownership and assignment agreements or provisions with certain of our employees, consultants, scientific advisors, contractors and commercial partners involved in research and development activities or who may otherwise have access to our confidential or proprietary information. These agreements are designed to protect our proprietary information. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, such agreements or security measures may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or others, which would significantly affect our competitive advantage and have a material adverse effect on our business, results of operation and financial condition. See also “Risk Factors—Risks Related to Our Intellectual Property—Under applicable U.S. and Israeli law, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.”

Raw Materials, Suppliers and Manufacturing

In order to produce Allocetra™, blood donations are collected from healthy donors through apheresis and then shipped to a manufacturing site for cryopreservation by trained personnel pursuant to cGMP requirements and otherwise in accordance with applicable FDA guidelines and our CMC protocols. The cells sourced for Allocetra™ then undergo quality control testing and are thawed and manipulated *ex vivo* by inducing apoptosis to retrieve and harvest stable early apoptotic cells. The agents used in the *ex vivo* manipulation for Allocetra™ are then washed and removed before the apoptotic cells are combined with a saline solution for delivery and injection in patients. We use standard collection equipment and procedures to collect blood for Allocetra™ production. Other than the blood collections, we believe that the raw materials required to manufacture our product candidates are readily available commodities commonly used in the pharmaceutical and biotechnology industries and are generally widely available from numerous suppliers at market prices. However, biologically sourced raw materials are subject to unique contamination risks and their use may be restricted in certain countries. See also "Risk Factors—Risks Related to our Business, Industry and Regulatory Requirements—Our manufacturing processes are complex, delicate and susceptible to contamination, and involve biological intermediates that are subject to stringent regulations," and "Risk Factors—Risks Related to our Business, Industry and Regulatory Requirements—Our ability to produce safe and effective products depends on the safety of our blood supply against transmittable diseases."

There can be no assurance that any of our product candidates, if approved, including Allocetra™, can be manufactured in sufficient commercial quantities, in compliance with regulatory requirements and at an acceptable cost. We and our any potential future contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products. We and our future contract manufacturers must ensure that all of the processes, methods and equipment are compliant with our CMC and cGMP for drugs and biologics on an ongoing basis, as mandated by EMA and other applicable regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers.

Clinical and Commercial Manufacturing

We manufacture Allocetra™ at our existing cGMP facility in our Ness Ziona site to accommodate our current clinical supply demand.

We previously also manufactured Allocetra™ at our facility in Yavne, Israel. However, as part of our strategic reprioritization plan adopted in September 2023, we entered into an agreement (the "Yavne Facility Sale Agreement") with BioHarvest Ltd., an Israeli company (the "purchaser") on March 31, 2024, pursuant to which the purchaser agreed to acquire the equipment installed by us in the Yavne facility (the "Equipment") and assume all of our obligations under the lease agreement for the Yavne facility, entered into in September 2021 (the "Lease Agreement"), effective as of April 1, 2024. For additional information, see Item 4.D. "Information on the Company— Property, Plants and Equipment."

We produce Allocetra™ as a frozen formulation, providing long-term storage stability at -80°C using liquid nitrogen, which has resulted in substantial efficiencies in our manufacturing operations compared to our prior non-frozen formulation. Our frozen formulation allows us to stockpile Allocetra™ for both short- and long-term storage and effectively manage our clinical supply and reduce potential waste. Moreover, local administration of Allocetra™ directly into a target joint is given at lower doses compared to systemic administration. In connection with the ongoing osteoarthritis clinical trials, in which Allocetra™ is administered directly into a target joint, we can manufacture a significant amount of Allocetra™ from a single doner for local administration and can better accommodate the clinical manufacturing demand utilizing a lower manufacturing capacity. Therefore, we expect to have sufficient manufacturing capacity to support our clinical trials for osteoarthritis.

Contract Research Organizations

We intend to outsource certain future clinical trial activities, including the administration of treatments, to CROs. Such clinical CROs must comply with guidelines from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, which attempt to harmonize the FDA and the EMA regulations and guidelines. We intend to create and implement the development plans and manage the CROs according to the specific requirements of the product candidate under development. To the extent clinical research is conducted by the CROs (or us in the future), compliance with certain federal regulations, including but not limited to 21 C.F.R. parts 50, 54, 56, 58 and 312, which pertain to, among other things, informed consent, financial conflicts of interest by investigators, IRBs, good laboratory practices, GCP and submitting IND applications, may be required.

Marketing, Sales and Commercialization

Given our stage of development, we do not have any internal sales, marketing or distribution infrastructure or capabilities. If we receive regulatory approval for any of our product candidates, we intend, as appropriate, to pursue commercialization relationships, including strategic alliances and licensing, with biotechnology companies and other strategic partners that are equipped to market and sell our products. In addition, we may out-license some or all of our worldwide patent rights to more than one party to achieve the fullest development, marketing and distribution of any products we develop. Over the longer term, we may consider building an internal marketing, sales and commercial infrastructure.

Environmental Matters

We, our agents and our service providers, including our manufacturers, are subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous and biological materials and wastes and the cleanup of contaminated sites. We believe that our business, operations and facilities, including, to our knowledge, those of our agents and service providers, are currently operated in compliance in all material respects with applicable environmental and health and safety laws and regulations. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on us. However, significant expenditures could be required in the future if we, our agents or our service providers are required to comply with new or more stringent environmental or health and safety laws, regulations or requirements.

Government Regulation

Clinical trials, the drug approval process and the marketing of drugs are extensively regulated in the United States and in all other major foreign countries. Governmental authorities in the United States (including federal, state and local authorities) and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, pricing and export and import of pharmaceutical products, such as those we are developing. The process for obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

European Union/Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial application ("CTA"), must be submitted for each clinical protocol to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is accepted in accordance with a country's requirements, the clinical trial may proceed.

The requirements and process governing the conduct of clinical trials vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP, the applicable regulatory requirements, and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational medicinal product under European Union regulatory systems, we must submit a marketing authorization application. The content of the NDA or BLA filed in the United States is similar to that required in the European Union, with the exception of, among other things, country and EU-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing product licensing, pricing, and reimbursement vary from country to country.

Countries that are part of the European Union, as well as countries outside of the European Union, have their own governing bodies, requirements, and processes with respect to the approval of pharmaceutical products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Authorization Procedures in the European Union

Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

Centralized procedure. The European Commission implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the EEA which is comprised of the 27 member states of the European Union plus Norway, Iceland, and Lichtenstein. This procedure results in a single marketing authorization issued by the European Commission that is valid across the EEA. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering; contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions; and officially designated orphan medicines.

For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA following a favorable eligibility request by the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.

Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the procedure laid down in the EU directive 2001/83 as amended and implemented into national legislation. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In some cases, a Pediatric Investigation Plan, or PIP, and/or a request for waiver or deferral, is required for submission prior to submitting a marketing authorization application. A PIP describes, among other things, proposed pediatric trials and their timing relative to clinical trials in adults.

New Chemical Entity Exclusivity

In the European Union, new chemical entities, sometimes referred to as new active substances or new molecular entities, as well as submissions following Article 8.3 of Directive 2001/83 as amended, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, the product may be approved but must not be launched prior to the end of the 10 years data exclusivity period. The overall ten-year period will be extended by one year if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, is held to bring a significant clinical benefit, in comparison with existing therapies, or by six months if there is a pediatric development in accordance with a PIP has been performed.

Orphan Drug Designation and Exclusivity

In the European Union, the EMA's COMP grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected, i.e. where a prior approval was granted). Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the medicinal product.

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. This period can be prolonged to 12 years in case a pediatric development has been performed following an agreed PIP.

Orphan drug designation must be requested and granted before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Exceptional Circumstances/Conditional Approval

Orphan drugs or drugs with unmet medical needs may be eligible for European Union approval under exceptional circumstances or with conditional approval. Approval under exceptional circumstances is applicable to all applications including orphan products and is used when an applicant is unable to provide comprehensive data on the efficacy and safety under normal conditions of use because the indication for which the product is intended is encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, when the present state of scientific knowledge does not allow comprehensive information to be provided, or when it is medically unethical to collect such information. Conditional marketing authorization is applicable to orphan medicinal products, medicinal products for seriously debilitating or life-threatening diseases, or medicinal products to be used in emergency situations in response to recognized public threats. Conditional marketing authorization can be granted on the basis of less complete data than is normally required in order to meet unmet medical needs and in the interest of public health, provided the risk-benefit balance is positive, it is likely that the applicant will be able to provide the comprehensive clinical data after approval, and unmet medical needs will be fulfilled. Conditional marketing authorization is subject to certain specific obligations to be reviewed annually. The initial approval needs to be renewed annually. This renewal is controlled by the CHMP and, if not granted, may lead to cessation of the marketing authorization at the end of this particular year.

Accelerated Review

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA's Committee for Medicinal Products for Human Use, or CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops.

U.S. Government Regulation

In the United States, the FDA regulates drugs and biologics under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and related regulations, and the Public Health Service Act (the "PHSA") and its implementing regulations. In addition, drug innovation, prescribing and reimbursement are influenced by Titles XVIII and XIX of the Social Security Act (commonly referred to as Medicare and Medicaid, respectively) and the Patient Protection and Affordable Care Act, 42 U.S.C. § 18001, as amended, and their implementing regulations. FDA approval is required before any new drug or biologic candidate or dosage form, including a new use of a previously approved drug, can be marketed in the United States. We intend to submit a BLA in the United States. Failure to comply with the applicable United States regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an IRB of a clinical hold on trials, the FDA's refusal to approve pending applications or supplements, license suspension or revocation, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, other corrective action, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA and foreign regulatory authorities impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising and promotion of our products.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our platforms and candidate products or any future product candidates or approval of new disease indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Marketing Approval

The process required by the FDA before a product candidate may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests and nonclinical animal studies, all performed in accordance with cGMP and current good laboratory practices, guidance and regulations;
- submission to the FDA of an investigational new drug ("IND"), application which must become effective before human clinical trials may begin and must be updated annually;
- approval by an IRB or ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- preparation of, and submission to the FDA, an NDA or BLA after completion of all clinical trials;
- potential review of the product application by an FDA Advisory Committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of FDA pre-approval inspection of the manufacturing facilities where the proposed product is produced to assess compliance with cGMP; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the drug in the United States.

The testing and approval processes require substantial time and financial resources, and we cannot be certain that any approvals for our candidate products will be granted on a timely basis, if at all.

An IND is a request for authorization from the FDA to administer an investigational new drug or biologic product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of in vitro and in vivo studies and animal testing results assessing the toxicology, pharmacokinetics and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

We will need to successfully complete clinical trials in order to be in a position to submit a BLA to the FDA. Our planned future clinical trials for our candidate products may not begin or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including:

- not obtaining regulatory approval to commence a trial;
- not reaching agreement with third-party clinical trial sites and their subsequent performance in conducting accurate and reliable studies on a timely basis;
- not obtaining IRB approval to conduct a trial at a prospective site;
- recruiting an insufficient number of patients to participate in a trial;
- inadequate supply of the drug; and
- clinical adverse finding(s) during the trial itself.

We must reach an agreement with the FDA on the proposed protocols for our future clinical trials in the United States. A separate submission apart from an IND application must be made for each clinical trial to be conducted during product development. Further, an independent IRB for each site proposed to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. Informed consent must also be obtained from each trial subject. Regulatory authorities, an IRB or the sponsor, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk.

Clinical trials

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators in accordance with current clinical practices ("GCP"), which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB before the studies may be initiated and the IRB must monitor the trial until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Our objective is to conduct clinical trials for our candidate products and, if those trials are successful, seek marketing approval from the FDA and other worldwide regulatory bodies.

For purposes of NDA approval, human clinical trials are typically conducted in phases that may overlap.

- *Phase 1*. The drug or biologic is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients;

- *Phase 2*. This phase involves trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage;

- *Phase 3*. This phase involves trials undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population, often at geographically dispersed clinical trial sites. These trials are intended to establish the overall benefit/risk profile of the product and provide an adequate basis for product labeling; and

- *Phase 4*. In some cases, the FDA may condition approval of an NDA or BLA for a product candidate on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase 4 clinical trials.

A pivotal trial is a clinical trial that adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal trials are Phase 3 trials, but the FDA may accept results from Phase 2 trials if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need and the results are sufficiently robust.

The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a DSMB or Committee. This group provides oversight and assessment of designated milestones based on access to certain data during the conduct of the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

All of these trials must be conducted in accordance with GCP requirements in order for the data to be considered reliable for regulatory purposes.

The clinical trial process can take three to ten years or more to complete and there can be no assurance that the data collected will support FDA approval or licensure of the product. Government regulation may delay or prevent marketing of a product candidate or new drugs for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approvals for a product candidate on a timely basis, if at all. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

The NDA and BLA Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational new drug product information is submitted to the FDA in the form of an NDA, and a BLA for new biologics, requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs and BLAs is subject to an application user fee. For the FDA's fiscal year 2024, the application user fee with clinical data was $4,048,695 and for 2025 the fee is $4,310,002. Additionally, the sponsor of an approved NDA or BLA is also subject to annual product and program user fees. For the FDA's fiscal year 2024, these program fees were $416,734 per product and for 2025, they are $403,889 per product. These fees are typically increased annually. Applications for orphan drug products are exempted from these user fees and may be exempted from product and establishment user fees, unless the application includes an indication for other than a rare disease or condition.

An NDA and BLA must include all relevant data available from pertinent nonclinical and clinical trials, regardless of the results or findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data is generated from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or in certain instances, from other sources, including trials initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational new drug product to the satisfaction of the FDA.

The FDA will initially review the NDA or BLA for completeness before it accepts it for filing. The FDA has 60 days from receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. After the NDA or BLA submission is accepted for filing, the FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an Advisory Committee, typically a panel that includes independent clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an Advisory Committee, but it considers such recommendations carefully when making decisions.

Upon the request of an applicant, the FDA may grant a Priority Review designation to a product, which sets the target date for FDA action on the application at six months, rather than the standard ten months. Priority review is given where preliminary assessments indicates that a product, if approved, has the potential to provide a significant improvement compared to marketed products or offers a therapy where no satisfactory alternative therapy exists. Priority Review designation does not alter the scientific/medical standard for approval or the quality of evidence necessary to support approval.

The FDA is required to complete its review in a certain amount of time, for which the user fees are paid to help with the costs of the evaluation. However, FDA and the sponsor can agree to extend this review time. After the FDA completes its review of an NDA or BLA, it will communicate to the sponsor that the drug or biologic will either be approved, or it will issue a Complete Response Letter to communicate that the NDA or BLA will not be approved in its current form and inform the sponsor of changes that must be made or additional clinical, nonclinical or manufacturing data that must be received before the application can be approved, with no implication regarding the ultimate approvability of the application.

Before approving an NDA or BLA, the FDA will typically inspect the facilities at which the drug substance or drug product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Additionally, before approving an NDA or BLA, the FDA may inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the NDA or BLA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process for a drug requires substantial time, effort and financial resources and this process may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 trials may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 trials can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA now has express statutory authority to require sponsors to conduct post-market trials to specifically address safety issues identified by the agency.

Any approvals that we may ultimately receive could be withdrawn if required post-marketing trials or analyses do not meet the FDA requirements, which could materially harm the commercial prospects for our candidate products.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy ("REMS"), from sponsors to ensure that the benefits of a drug or biological product outweigh its risks. A sponsor may also propose a REMS as part of the NDA or BLA submission. The need for a REMS is determined as part of the review of the NDA or BLA. Based on statutory standards, elements of a REMS may include "Dear Doctor" letters, a "Medication Guide", more elaborate targeted educational programs and in some cases restrictions on distribution. These elements are negotiated as part of the NDA or BLA approval, and in some cases if consensus is not obtained until after the Prescription Drug User Fee Act review cycle, the approval date may be delayed. Once adopted, REMS are subject to periodic assessment and modification.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, including Black Box Warnings, or in the form of risk management plans, restrictions on distribution, or post-marketing trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for our candidate products, or obtaining approval but for significantly limited use, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

FDA Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, changes to the approved product or the addition of new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

Drug sponsors and their manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our current product candidate, and expect to rely in the future on third parties for the production of commercial quantities. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of a requirement to conduct post-market trials or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, but not limited to the following:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or BLAs or supplements to approved NDAs or BLAs, or suspension or revocation of product license approvals;
- injunctions or the imposition of civil or criminal penalties; or
- product seizure or detention, or refusal to permit the import or export of products.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant enforcement and product liability exposure.

Orphan Drug Designation and Exclusivity

The FDA may grant orphan drug designation to drugs and biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug or biologic for this type of disease or condition will be recovered from sales in the United States.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and FDA user-fee waivers. In addition, if a product receives FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. Orphan drug designation does not affect the regulatory review standards or shorten the review period. Designation does not imply FDA approval, and it is possible a company may, in certain cases, lose designation before a product's approval and, thus, may not obtain orphan drug exclusivity.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug or biologic products for which we may obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payers. Third-party payers include government authorities, managed care providers, private health insurers and other organizations. If we obtain regulatory approval for our products, third-party payers may not provide coverage for our products, or may limit coverage to specific drug or biologic products on an approved list, or formulary, which might not include all of the FDA-approved drugs and biologics for a particular indication. Moreover, a payer's decision to provide coverage for a drug or biologic product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any product that receives regulatory approval for commercial sale, we may need to provide supporting scientific, clinical and cost-effectiveness data, which may be difficult and costly to obtain. Our current or any future product candidates may not be considered medically necessary or cost-effective. If third-party payers do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of health care costs, including price controls, reporting requirements, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. By way of example, the ACA contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of additional government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals.

In the U.S., judicial challenges as well as legislative initiatives to modify, limit, or repeal the ACA have been initiated and continue. The extent to which any repeal or replacement of elements of the ACA, or other legislation, would affect our ability to obtain regulatory approval for the sale of Allocetra™, or the prices and net revenues from its sale is unknown at the time of this filing and represent an additional uncertainty.

In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules, legislation and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

In Canada, the federal government, provinces and territories provide coverage to about one third of residents through publicly financed programs. Both the federal and provincial governments play a role in regulating drug prices and reimbursement. The prices of patented drugs are regulated at the federal level by the Patented Medicine Prices Review Board, which ensures that prices are not excessive. Also, drugs must be approved at the provincial level in order to be covered under provincial health insurance systems. Once Health Canada has approved a drug for use, the country's public drug plans must decide if the drug will be eligible for public reimbursement. The Canadian Agency for Drugs and Technologies in Health ("CADTH"), an independent non-profit agency has a mandate to provide advice and evidence-based information about the effectiveness of drugs and other health technologies to Canadian health care decision makers. CADTH implements a Common Drug Review ("CDR") process to provide formulary recommendations for all provinces except Quebec. Through the CDR process, CADTH conducts evaluations of the clinical, economic, and patient evidence on drugs, and uses this evaluation to provide reimbursement recommendations and advice to Canada's federal, provincial, and territorial public drug plans, with the exception of Quebec. About two-thirds of Canada's residents are covered for prescription drugs by private insurance. Private plans establish their own lists of covered drugs.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if governmental and other third-party payers fail to provide adequate coverage and reimbursement. In addition, there is an increasing emphasis on cost containment measures in the United States and other countries, which we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

If we obtain regulatory approval for our current or any future product candidates, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or reward, or in return for, the referral of an individual, or the purchase, order or recommendation of any good, item or service reimbursable under a federal healthcare program, such as Medicare and Medicaid;

- the federal physician self-referral prohibition law, or Stark Law, which prohibits, among other things, a physician (defined to include a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor) from referring Medicare and Medicaid patients to certain types of entities with which the physician or any of the physician's immediate family members have a financial relationship;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from the federal government, including Medicare, Medicaid, or other third-party payers, that are false or fraudulent;

- federal health care fraud, which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, and for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency laws, including the physician sunshine provisions of the Affordable Care Act, that requires certain pharmaceutical manufacturers to disclose certain payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their family members;

- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, which imposes certain requirements relating to the privacy and security of individually identifiable health information;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and

- the FCPA, which prohibits companies from making improper payments to foreign government officials and other persons for the purpose of obtaining or retaining business.

In the United States, the research, manufacturing, distribution, sale and promotion of drug and biologic products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare& Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other federal, state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with, among others, the federal Anti-Kickback Statute, the Stark Law, the federal False Claims Act, privacy and security regulations promulgated under HIPAA, and similar state laws, as applicable. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The ACA broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. §1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only federal healthcare programs such as the Medicare and Medicaid programs.

Safeguards we implement to prohibit improper payments or offers of payments by our employees, consultants, and others may be ineffective, and violations of the fraud and abuse laws, the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and result of operations.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, damages, fines, disgorgement, contractual remedies, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Labeling, Marketing and Promotion

The FDA closely regulates the labeling, marketing and promotion of drugs and biologics. While doctors are free to prescribe any drug or biologic approved by the FDA for any use, a company can only make claims relating to safety and efficacy of a drug that are consistent with FDA approval, and the company is allowed to actively market a drug or biologic only for the particular use and treatment approved by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, enforcement letters, such as publicly-posted warning letters, corrective advertising, injunctions and potential civil and criminal penalties. Government regulators recently have increased their scrutiny of the promotion and marketing of drugs and biologics. These federal enforcement actions can also potentially lead to state actions and product liability claims, as well as competitor challenges of deceptive advertising.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Israel

Clinical Testing in Israel

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

4.C. Organizational Structure

We have the following wholly owned subsidiaries: (i) Enlivex Therapeutics R&D Ltd., a company organized under the laws of the State of Israel; (ii) Enlivex Therapeutics Inc., a Delaware corporation; and (iii) Enlivex Therapeutics RDO Ltd., a company organized under the laws of the State of Israel.

4.D. Property, Plants and Equipment

Our corporate headquarters are located at 14 Einstein Street, Ness Ziona, Israel 7403618, where we lease approximately 420 square meters of space under an agreement with a current term through August 2028. The facility includes office space, laboratories and cGMP clean rooms, in which we manufacture clinical batches to support our clinical trials in Israel and the EU. In October 2020, we entered into a lease agreement for additional office space and a laboratory at our Ness Ziona, Israel facility, of approximately 421 square meters of space. The lease for this space expires on September 30, 2025, at which time we may extend the lease for an additional 33-month period.

In July 2021, we entered into an additional lease agreement for approximately 455 square meters of office space in an adjacent building in Ness Ziona, Israel. The lease for this office space expires on October 31, 2026, and we have the option to extend the lease for an additional 22-month period. As part of our strategic reprioritization plan announced in September 2023, we decided in 2024 to sell the lease rights under such lease agreement, along with the leasehold improvements installed by us in the leased property. On January 29, 2025, we completed the sale of this group of assets, which included the right-of-use asset for this leased property, the leasehold improvements installed in the property, and certain laboratory equipment, for a total amount of NIS 100,000 (approximately $27,000).

In September 2021, we entered into the Lease Agreement for a 2,500 square meter property in Yavne, Israel to construct a new 1,600 square meter facility for the manufacture of Allocetra™, which was completed in the fourth quarter of 2022. As part of our strategic reprioritization plan, we determined to sell such leased manufacturing facility, together with the Equipment, and assign the Lease Agreement. On March 31, 2024, we entered into the Yavne Facility Sale Agreement with the purchaser, pursuant to which the purchaser agreed to acquire the Equipment and assume all of our obligations under the Lease Agreement, effective as of April 1, 2024, for an aggregate purchase price of NIS 13.0 million (approximately $3.5 million). The purchase price is payable in installments, consisting of an initial payment of NIS 4.0 million (approximately $1.08 million), which was paid on April 2, 2024, and 24 equal monthly installment payments of NIS 375,000 (approximately $102,000), which commenced on April 1, 2024. As of December 31, 2024, the Company had received a total of NIS 7.75 million (approximately $2.1 million) under the Yavne Facility Sale Agreement. Pursuant to the Yavne Facility Sale Agreement, title to the Equipment will transfer to the purchaser only upon full payment of the total purchase price, but risk of loss to the Equipment passed to the purchaser on April 1, 2024. Subject to certain conditions, the purchaser may, in its sole discretion, prior to October 1, 2025, prepay (i) all of the remaining outstanding purchase price at a 4% discount, or (ii) a portion of the remaining outstanding purchase price, in an amount of not less than NIS 4.0 million (approximately $1.08 million), at a 2% discount, in which case, the purchase price remaining outstanding thereafter shall continue to be paid in monthly instalments of NIS 375,000 each (approximately $102,000).

We believe that our facilities are suitable and adequate for our current needs.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 20-F. The following discussion and analysis contains forward-looking statements that involve risk and uncertainties, such as statements regarding our plans, objectives, expectations, and intentions. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Cautionary Note Regarding Forward-Looking Statements", "Risk Factor Summary" and Item 3.D. "Risk Factors" contained in this Annual Report on Form 20-F.

Overview

The Company is a clinical-stage macrophage reprogramming immunotherapy company, developing Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state. Resetting non-homeostatic macrophages into their homeostatic state is critical for immune system rebalancing and resolution of debilitating and life-threatening conditions. Non-homeostatic macrophages contribute significantly to the severity of the respective disease. By restoring macrophage homeostasis, Allocetra™ has the potential to provide a novel immunotherapeutic mechanism of action for debilitating and life-threatening clinical indications that are defined as "unmet medical needs," as a stand-alone therapy or in combination with leading therapeutic agents.

We believe the Company's primary innovative immunotherapy, Allocetra™, represents a paradigm shift in macrophage reprogramming, moving from targeting a specific subset of macrophages or a specific pathway affecting macrophage activity, to a fundamental view of macrophage homeostasis. Restoring macrophage homeostasis may induce the immune system to rebalance itself to normal levels of operation, thereby promoting disease resolution.

The Company is focused on osteoarthritis as its main inflammatory indication. Osteoarthritis is a degenerative joint disease, characterized by low-grade inflammation, that affects more than 32.5 million adults in the United States. Treatment of osteoarthritis represents a substantial unmet medical need, particularly non-invasive treatments, as current therapeutic options are largely limited to pain management, lifestyle modifications, and, ultimately, joint replacement surgery. The Company believes that negatively reprogrammed macrophages may be key contributors to disease severity in osteoarthritis and that the effective reprogramming of these negatively reprogrammed macrophages into their respective homeostatic states may facilitate disease resolution. For details of the Company's osteoarthritis clinical trials, see Item 4.B. "Information on the Company—Business Overview—— Osteoarthritis Clinical Program."

During 2024, the Company also continued the development of its sepsis clinical program and announced the 28-day topline data from the Phase II trial evaluating Allocetra™ in patients with sepsis. For details of the Company's sepsis clinical trials, see Item 4.B. "Information on the Company—Business Overview—— Sepsis Clinical Program." In light of market conditions, the Company's limited cash availability and the substantial budget required for advancing to a follow-up clinical trial in patients with sepsis, the Company plans to seek potential external collaboration or out-licensing opportunities for the continued clinical development of Allocetra™ for use in patients with sepsis, instead of pursuing internal development.

5.A. Operating Results

Financial Overview

Since inception, we have incurred significant losses in connection with our research and development and have not generated any revenue. We have funded our operations primarily through grants from the IIA and the sale of equity and equity linked securities in public and private offerings. As of December 31, 2024, we had approximately $23.5 million in cash and cash equivalents and short-term bank deposits and had an accumulated deficit of approximately $127.1 million. See "—Liquidity and Capital Resources" below.

We expect that we will continue to incur operating losses in connection with our research and development activities, which may be substantial over the next several years, and we expect to require additional funds to further pursue our research and development programs.

Revenue

We have not generated any revenue since our inception. To date, we have funded our operations primarily through grants from the IIA and the sale of equity and equity linked securities in public and private offerings. Our ability to generate revenue and become profitable depends upon the clinical success of our product candidates, regulatory approvals and our ability to successfully commercialize products.

Costs and Operating Expenses

Our current costs and operating expenses consist of two components: (i) research and development expenses, net; and (ii) general and administrative expenses.

Research and Development Expenses, Net

Our research and development expenses consist primarily of research and development activities at our laboratory in Israel, including drug and laboratory supplies and costs for facilities and equipment, outsourced development expenses, including the costs of regulatory consultants and certain other service providers, salaries and related personnel expenses (including share-based compensation) and fees paid to external service providers and the costs of preclinical studies and clinical trials. We charge all research and development expenses to operations as they are incurred. We expect our research and development expenses to remain our primary expenses in the near future as we continue to develop Allocetra™. Increases or decreases in research and development expenditures are attributable to the number and duration of our preclinical and clinical studies.

Grants received from the IIA are recognized when the grant becomes receivable, provided there is reasonable assurance that (i) we will comply with the conditions attached to the grant and (ii) the grant will be received. Research and development expenses, net, is reduced to the extent we receive IIA grants.

We expect that a large percentage of our research and development expenses in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes, we are unable to estimate with any certainty the costs we will incur for the continued development of our product candidates in our pipeline for potential commercialization. Furthermore, although we expect to apply for additional IIA grants, we cannot be certain that we will obtain such grants. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy and to conduct additional clinical trials for our product candidates.

While we are currently focused on advancing our product development, our future research and development expenses will depend on the clinical success of our product candidates, as well as ongoing assessments of each candidate's commercial potential. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for our product candidates in certain indications in order to focus our resources on more promising indications for any such product candidate, which is illustrated by some of the steps we have taken in respect of our reprioritization plan described in Item 4 of this Annual Report on Form 20-F. Completion of clinical trials may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate.

We expect our research and development expenses to increase in the future as we continue the advancement of our clinical product development for our current indication and as we potentially pursue additional indications. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our financial condition and results of operation.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and related benefits (including share-based compensation) for employees in executive and operational roles, including accounting, finance, investor relations, information technology and human resources. Our other significant general and administrative expenses include facilities costs, professional fees for outside accounting and legal services, including legal work in connection with patent applications, travel costs and insurance premiums. We expect that our general and administrative expenses will decrease in 2025.

Finance Income (Expenses), Net

Finance income (expenses), net consists of interest earned on our cash and cash equivalents and bank deposits, exchange rate differences, gains and losses resulting from our investments in marketable securities, and bank fees and other expenses.

Results of Operations

For a discussion of our results of operations for the year ended December 31, 2022, including a year-to-year comparison between 2023 and 2022, and a discussion of our liquidity and capital resources for the year ended December 31, 2022, refer to Item 5. *"Operating and Financial Review and Prospects"* in our Annual Report on Form 20-F for the year ended December 31, 2023.

Year Ended December 31, 2024 Compared to Year Ended December 31, 2023

The table below provides our results of operations for the years ended December 31, 2024 and 2023:

	Year Ended December 31	
	2024	**2023**
	(In thousands, except per share data)	
Research and development expenses, net	$ 10,623	$ 19,012
General and administrative expenses	4,913	6,139
Other expenses	352	4,244
Operating loss	15,888	(29,395)
Finance income, net	874	327
Net loss	(15,014)	(29,068)
Total comprehensive loss	$ (15,014)	$ (29,068)
Basic loss per share	$ (0.73)	$ (1.56)
Diluted loss per share	$ (0.73)	$ (1.56)

Research and Development Expenses, Net

For the years ended December 31, 2024 and 2023, we incurred research and development expenses, net in the aggregate of $10,623,000 and $19,012,000, respectively. The decrease of $8,389,000, or 44%, in research and development expenses, net, for 2024, as compared to 2023, was primarily due to the implementation of our strategic reprioritization plan, which resulted in a $6,141,000 decrease in expenses for clinical studies, due to changes in our development programs, and purchase of materials, due to a decrease in the number of Allocetra™ doses that were manufactured, and a $2,187,000 decrease in salaries due to workforce reductions under the plan.

General and Administrative Expenses

For the years ended December 31, 2024 and 2023, we incurred general and administrative expenses of $4,913,000 and $6,139,000, respectively. The decrease of $1,226,000, or 20%, in general and administrative expenses for 2024, as compared to 2023, was primarily due to a $278,000 decrease in expense with respect to equity awards granted to directors, officers and employees, a $216,000 decrease in insurance expenses (due to a decrease in our directors' and officer's liability insurance premium), and a $801,000 decrease in lease and overhead expense due to the implementation of our strategic reprioritization plan.

Other Expenses

In 2023, as part of our strategic reprioritization plan, we determined to sell our leased manufacturing plant facility in Yavne, Israel, together with the Equipment, and assign the Lease Agreement for the property. Therefore, the right of use of the manufacturing plant, the lease liability relating to the manufacturing plant and the leasehold improvements installed in the leased plant were classified as assets held for sale and liability held for sale (as applicable) as of December 31, 2023. As a result, for the year ended December 31, 2023, we recognized a loss of $4,244,000 on the group of assets held for sale related to the Yavne facility. On March 31, 2024, we entered into the Yavne Facility Sale Agreement with the purchaser, pursuant to which the purchaser agreed to acquire the Equipment and assume all of our obligations under the Lease Agreement, effective as of April 1, 2024 for an aggregate purchase price of NIS 13.0 million (approximately $3.5 million). The purchase price is payable in installments, consisting of an initial payment of NIS 4.0 million (approximately $1.08 million), which was paid on April 2, 2024, and 24 equal monthly installment payments of NIS 375,000 (approximately $102,000), which commenced on April 1, 2024. Pursuant to the Yavne Facility Sale Agreement, title to the Equipment will transfer to the purchaser only upon full payment of the total purchase price, but risk of loss to the Equipment passed to the purchaser on April 1, 2024. For the year ended December 31, 2024, we recorded an additional $470,000 loss on the group of assets held for sale related to the Yavne facility.

In 2024, the Company decided to sell the lease rights under the lease agreement for certain of its leased property in Ness Ziona, Israel, which was entered into in July 2021, along with the leasehold improvements installed in the property and certain laboratory equipment. As of December 31, 2024, the Company had identified a potential purchaser and negotiated a potential transaction for the sale of these assets, which transaction was completed on January 29, 2025. Therefore, the right of use of such manufacturing plant, the lease liability relating to the manufacturing plant and the leasehold improvements installed in the leased plant were classified as assets held for sale and liability held for sale (as applicable) as of December 31, 2024. For the year ended December 31, 2024, the Company recognized a loss of $487,000 on the group of assets held for sale related to this Ness Ziona facility.

In addition, for the year ended December 31, 2024, the Company recognized income of $605,000 from the cancelation of a liability related to uncertain tax positions.

Operating Loss

For the year ended December 31, 2024, our operating loss was $15,888,000 as compared to $29,395,000 for the year ended December 31, 2023, representing a decrease of $13,507,000 or 46%. The decrease was primarily due to the implementation of our strategic reprioritization plan, which resulted in a reduction in research and development expenses, including a decrease in clinical trial expenses due to changes in our clinical programs and a decrease in salaries as a result of the reduction in workforce as part of the plan, and a decrease in lease and overhead expenses.

Finance Income, Net

For the year ended December 31, 2024, we recorded finance income, net of $874,000 as compared to $327,000 for the year ended December 31, 2023. The increase in finance income, net for the year ended December 31, 2024, as compared to the year ended December 31, 2023, was primarily due to $1,069,000 of interest income earned on cash equivalents and bank deposits in 2024, offset by a loss of $182,000 resulting from foreign exchange currency fluctuations, as compared to interest income of $1,565,000 on cash equivalents and bank deposits in 2023, partially offset by a loss of $1,224,000 resulting from foreign exchange currency fluctuations.

Net Loss

For the year ended December 31, 2024, our net loss was $15,014,000, as compared to $29,068,000 for the year ended December 31, 2023, a decrease of $14,054,000, or 48%. This decrease in net loss was primarily due to a decrease in operating loss and an increase in finance income, net

Cash Flows

For the years ended December 31, 2024 and 2023, net cash used in operations was $13,008,000 and $23,523,000, respectively. The decrease in net cash used in operations for 2024 was primarily due to decreases in payments to suppliers, service providers and employees as result of a decrease in payroll and rent expenses, as well as a decrease in research and development expenses, mainly from decreased clinical study expenses.

For the year ended December 31, 2024, net cash provided by investing activities was $9,059,000, compared to net cash used in investing activities of $25,968,000 for the year ended December 31, 2023. The increase in net cash provided by investing activities in 2024, compared to 2023, was primarily due to the net release of investment in short-term interest-bearing bank deposits amounting to $6,869,000 in 2024, as compared to a net investment in short-term interest-bearing bank deposits of $25,865,000 in 2023, as well as due to proceeds of $2,109,000 from the sale of assets and liabilities classified as held for sale.

For the years ended December 31, 2024 and 2023, net cash provided by financing activities was $6,454,000 and $360,000, respectively. The increase in cash provided by financing activities for 2024 as compared to 2023 resulted primarily from net proceeds of $4,416,000 from our issuance of ordinary shares and warrants in the May 2024 Offering (as defined below) and net proceeds of $2,036,000 from our issuance of ordinary shares under the ATM Agreement (as defined below) in 2024, as compared to net proceeds of $360,000 from our issuance of ordinary shares under the ATM Agreement in 2023.

5.B. Liquidity and Capital Resources

We have incurred substantial losses since our inception. As of December 31, 2024, we had an accumulated deficit of approximately $127.1 million and working capital (current assets less current liabilities) of approximately $22.2 million. We expect to incur losses from operations for the foreseeable future.

Developing product candidates, conducting clinical trials and commercializing products are expensive, and we will need to raise substantial additional funds to achieve our strategic objectives. We believe that our existing cash resources will be sufficient to fund our projected cash requirements approximately through the end of 2026. Nevertheless, we will require significant additional financing in the future to fund our operations, including if and when we progress into additional clinical trials, obtain regulatory approval for any of our product candidates and commercialize the same. We believe that we will need to raise significant additional funds before we have any cash flow from operations, if at all. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues and contributions we receive under future licensing, development and commercialization arrangements with respect to our product candidates;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval for our product candidates;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of contracting with third parties to provide sales and marketing capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future products, product candidates or platforms;

- receipt of additional government grants;
- the magnitude of our general and administrative expenses; and
- any cost that we may incur under future in- and out-licensing arrangements relating to our product candidates.

Other than under our ATM Agreement, we currently do not have any agreements for future external funding. In the future, we will need to raise additional funds, and we may decide to raise additional funds even before we need such funds if the conditions for raising capital are favorable. Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through debt or equity financings, credit facilities or by out-licensing applications of our product candidates. The sale of equity, including under our ATM Agreement, or convertible debt securities may result in dilution to our existing shareholders. The incurrence of indebtedness would result in increased fixed obligations and could also subject us to covenants that restrict our operations. We cannot be certain that additional funding, whether through grants from the IIA, financings, credit facilities or out-licensing arrangements, will be available to us on acceptable terms, if at all. If sufficient funds are not available, we may be required to delay, reduce the scope of or eliminate research or development plans for, or commercialization efforts with respect to, one or more applications of our product candidates, or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain potential products that we might otherwise seek to develop or commercialize independently.

May 2024 Financing

On May 27, 2024, we entered into a securities purchase agreement with a single institutional investor in connection with the issuance and sale in a registered direct offering (the "May 2024 Offering") of (i) 2,060,000 of our ordinary shares, (ii) pre-funded warrants to purchase up to 1,511,429 ordinary shares (the "Pre-Funded Warrants"), (iii) Series A warrants to purchase up to 3,571,429 ordinary shares (the "Series A Warrants") and (iv) Series B warrants to purchase up to 3,571,429 ordinary shares (the "Series B Warrants" and, together with the Series A Warrants, the "Investor Warrants"), at a combined purchase price of (a) $1.40 per ordinary share and the associated Investor Warrants, each to purchase one ordinary share, and (b) $1.399 per Pre-Funded Warrant and the associated Investor Warrants, each to purchase one ordinary share, pursuant to the Company's effective shelf registration statement on Form F-3 (File No. 333-264561) and a related base prospectus, together with the related prospectus supplement, dated as of May 27, 2024, filed with the SEC.

Each Investor Warrant is exercisable at an exercise price of $1.40 per ordinary share. The Series A Warrants expire upon the earlier of 18 months following the issuance date and 60 days following our public announcement of positive topline results from the ENX-CL-05-001 trial of Allocetra™ for the treatment of moderate-to-severe knee osteoarthritis. The Series B warrants expire upon the earlier of five and one-half years following the issuance date and 60 days following our public announcement of our filing with the FDA for approval for Allocetra™'s osteoarthritis related indication. Each Pre-Funded Warrant is exercisable at an exercise price of $0.001 per ordinary share, may be exercised at any time and has no expiration date. The Investor Warrants and the Pre-Funded Warrants are subject to customary adjustments; however, no such warrants contain any "ratchet" or other financial antidilution provisions. None of the Investor Warrants may be exercised if the aggregate number of ordinary shares beneficially owned by the holder thereof would exceed 4.99% immediately after exercise thereof, subject to increase to 9.99% at the option of the holder. None of the Pre-Funded Warrants may be exercised if the aggregate number of ordinary shares beneficially owned by the holder thereof would exceed 9.99% immediately after exercise thereof.

H.C. Wainwright & Co. ("Wainwright") acted as placement agent in connection with the May 2024 Offering, and in consideration therefor we agreed to register and issue to Wainwright warrants (the "Placement Agent Warrants") to purchase up to 250,000 of our ordinary shares pursuant to the above noted registration statement. The Placement Agent Warrants comprise Series A Warrants to purchase 125,000 of our ordinary shares and Series B Warrants to purchase 125,000 of our ordinary shares, containing the same terms as the Investor Warrants, except that they are exercisable at a price of $1.75 per ordinary share, and the Series B Warrants will expire upon the earlier of five years following the commencement of the sale of the securities offered in the May 2024 Offering and 60 days following the public announcement of our filing with the FDA for approval for Allocetra™'s osteoarthritis related indication. The net proceeds from the May 2024 Offering were approximately $4,416,000 after deducting Wainwright's fees and other offering expenses.

ATM Agreement

On December 30, 2022, we entered into an agreement (the "ATM Agreement") with Cantor Fitzgerald & Co. and JMP Securities LLC (each referred to as an "Agent", and together, the "Agents"), as sales agents, pursuant to which we may elect to sell, but are not obligated to sell, ordinary shares having an aggregate offering price of up to $100,000,000 from time to time through the Agents. Our offer and sale of ordinary shares under the ATM Agreement may be made in transactions deemed to be "at-the-market" offerings as defined in Rule 415 under the Securities Act, including sales made directly on or through the Nasdaq Capital Market, or any other existing trading market in the United States for the ordinary shares, sales made to or through a market maker other than on an exchange or otherwise, directly to an Agent as principal, in negotiated transactions, or in any other method permitted by law, which may include block trades. We have agreed to pay the Agents an aggregate commission of 3.0% of the gross sales price from each sale of ordinary shares under the ATM Agreement. Any sale of ordinary shares under the ATM Agreement will be made pursuant to our effective shelf registration statement on Form F-3, including the prospectus contained therein (File No. 333-264561). During 2024, we received aggregate net proceeds of approximately $2,036,000 from the sale of 1,305,014 ordinary shares under the ATM Agreement.

Because our current registration statement on Form F-3 (File No. 333-264531) will expire in June 2025, we expect to file a replacement for such registration statement and concurrently amend, to the extent necessary, the ATM Agreement in connection with such filing. Because the price of our ordinary shares has declined over the past year, we expect that our ability to issue and sell registered securities under such replacement registration statement will be limited by the "baby shelf" rules, which generally limit the amount of securities we may sell under such registration statement to 33% of our unaffiliated public float within any given 12-month period.

Certain Contractual Obligations

We are a party to contractual obligations involving commitments to make payments to third parties. These obligations impact our short-term and long-term liquidity and capital resource needs. Certain contractual obligations are reflected on the consolidated balance sheet as of December 31, 2024, while others are considered future commitments. Our contractual obligations primarily consist of lease payments. For information regarding our leases, see Item 4.D. "Information on the Company— Property, Plants and Equipment." For information regarding our contractual obligations, see Note 9 (Leases) to our audited consolidated financial statements included elsewhere in this Annual Report on Form 20-F.

5.C. Research and Development, Patents and Licenses, Etc.

For our research and development efforts, see Item 4.B. "Information on the Company—Business Overview." For information regarding our patents and proprietary rights, see Item 4.B. "Information on the Company—Business Overview—Intellectual Property and Patents and Proprietary Rights." For information regarding our license agreements, see Item 4.B. "Information on the Company—Business Overview—License Agreements."

5.D. Trend Information

We are a clinical-stage macrophage reprogramming immunotherapy company, and it is not possible for us to predict with any degree of accuracy the outcome of our research, development or commercialization efforts. As such, it is not possible for us to predict with any degree of accuracy any known trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our financial condition, including our liquidity and capital resources, or that would cause reported financial information to not necessarily be indicative of future operating results or financial conditions. Our results of operations and financial condition may be affected by various trends and factors discussed in Item 3.D. "Risk Factors," Item 4 "Information on The Company" and elsewhere in this Item 5 "Operating and Financial Review and Prospects."

5.E. Critical Accounting Estimates

Our audited financial statements included in this Annual Report on Form 20-F have been prepared in accordance with GAAP. The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Management bases its estimates on historical experience, market and other conditions, and various other assumptions it believes to be reasonable. Although these estimates are based on management's best knowledge of current events and actions that may impact us in the future, the estimation process is, by its nature, uncertain given that estimates depend on events over which we may not have control. If market and other conditions change from those that we anticipate, our financial statements may be materially affected. In addition, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material effect on our financial statements. We review our estimates, judgments, and assumptions used in our accounting practices periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that these estimates are reasonable; however, our actual results may differ from these estimates.

While our significant accounting policies are described in more detail in the notes to our financial statements contained elsewhere in this Annual Report on Form 20-F, we believe the following accounting policies to be the most critical to the judgments and estimates used in the preparation of our financial statements.

Share-Based Compensation

We have issued restricted stock units and options to purchase our ordinary shares. Share-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service/vesting period. Determining the appropriate fair value model and calculating the fair value of share-based payment awards require the use of highly subjective assumptions, including the expected life of the share-based payment awards and share price volatility.

We estimate the grant date fair value of share options and the related compensation expense, using the Black-Scholes option valuation model. This option valuation model requires the input of subjective assumptions including: (1) expected life (estimated period of time outstanding) of the options granted, (2) volatility, (3) risk-free rate and (4) dividends. In general, the assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but the estimates involve inherent uncertainties and the application of management judgment.

Leases

We determine if an arrangement includes a lease at inception. Right-of-use assets represent our right to use an underlying asset for the lease term; and lease liabilities represent our obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at the commencement date of the lease, renewal date of the lease or significant remodeling of the lease space based on the present value of the remaining future minimum lease payments. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. The interest rate implicit in lease contracts is typically not readily determinable. As a result, we utilize our incremental borrowing rate to discount lease payments, which reflects the fixed rate at which we could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

Our leases include options to extend or terminate the lease. In determining the lease term, management uses its judgement to determine whether or not an option would be reasonably certain to be exercised. Management considers all facts and circumstances including their past practice and any cost that will be incurred to change the asset if an option to extend is not taken to help determine the lease term. Extension options are only included in the lease term if the lease is reasonably certain to be extended.

Accrued clinical trial expenses

We record costs for clinical trial activities based upon estimates of costs incurred through the balance sheet date that have yet to be invoiced by the contract research organizations and other vendors.

Information necessary to estimate the accruals for the services that have been received during the reporting period is accumulated from multiple sources, including our personnel who oversee the clinical trial activities, information from service providers and terms and conditions included in the contracts with the service providers. In addition, in certain circumstances, the determination of the nature and level of services that have been received during the reporting period requires judgment because the historical timing and pattern of vendor invoicing does not correspond to the level of services provided, and there may be delays in invoicing from clinical study sites and other vendors.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

6.A. Directors and Executive Officers

The following table lists the names and positions of the current executive officers and directors of the Company. The business address for each of our directors, senior management and executive officers is c/o Enlivex Therapeutics Ltd., 14 Einstein Street, Ness Ziona, Israel 7403618.

Name	Age	Position
Shai Novik, MBA	59	Executive Chairman of the Board
Roger Pomerantz, M.D.	68	Director and Vice Chairman of the Board
Oren Hershkovitz, Ph.D.	48	Chief Executive Officer
Shachar Shlosberger, CPA	48	Chief Financial Officer
Einat Galamidi, M.D.	51	Chief Medical Officer
Abraham (Avri) Havron, Ph.D.	77	Director
Gili Hart, Ph.D.	50	Director
Andrew Singer	54	Director

Backgrounds of Current Executive Officers and Directors

Shai Novik has served as the Company's Executive Chairman of the Board of Directors since 2014. Mr. Novik previously founded PROLOR Biotech in 2005 and served as its President until 2013. PROLOR Biotech was listed on the NYSE in 2010 and was sold in 2013, in a $590 million transaction. Mr. Novik executed a strategic partnership with Pfizer for PROLOR's lead drug product, Ngenla®, and Pfizer continued with the clinical development of two-Phase III trials. Ngenla® recently obtained marketing approvals in 43 countries, including Australia, Canada, Japan, Europe & USA. Mr. Novik is the co-founder and a board member of Cortex Therapeutics, which is focused on developing and commercializing prescription digital therapies for patients with age-related diseases including macular degeneration (AMD) and presbyopia. Mr. Novik received his M.B.A. degree, with distinction, from Cornell University.

Roger Pomerantz, M.D. has served as a director and Vice Chairman of the Board of Directors since May 2022. Dr. Pomerantz has served as Chairman of the board of directors and Chief Executive Officer of ContraFect Corporation (Nasdaq: CFRX), a clinical-stage biotechnology company, since April 2019. Prior to that, Dr. Pomerantz served as Vice Chairman of the board of directors of ContraFect Corporation since May 2014. From November 2013 to December 2019, Dr. Pomerantz served as Chairman of the board of directors of Seres Therapeutics, Inc. (Nasdaq: MCRB), a biotechnology company, and as its President and Chief Executive Officer from June 2014 to January 2019. From 2011 to 2013, Dr. Pomerantz was formerly Worldwide Head of Licensing & Acquisitions, Senior Vice President at Merck & Co., Inc. where he oversaw all licensing and acquisitions at Merck Research Laboratories. Previously, Dr. Pomerantz served as Senior Vice President and Global Franchise Head of Infectious Diseases at Merck. Prior to joining Merck, Dr. Pomerantz was Global Head of Infectious Diseases for Johnson & Johnson Pharmaceuticals. Dr. Pomerantz joined Johnson & Johnson in 2005 as President of Tibotec Pharmaceuticals, Inc. Dr. Pomerantz serves as Chairman of the board of directors of the public companies Collplant Biotechnologies, Ltd. (Nasdaq: CLGN) since 2021, Indaptus Therapeutics, Inc. (Nasdaq: INDP) since 2021 and Viracta Therapeutics Inc (Nasdaq: VIRX) since 2020. Dr. Pomerantz also serves as Chairman of the board of directors of the private company Silicon Therapeutics Inc. since 2019, and a member of the board of the private companies X-VAX Technology, Inc. since 2019 and VerImmune since 2020. Previously, Dr. Pomerantz served on the board of directors of public companies Rubius Therapeutics from 2014 to 2019 and Evelo Therapeutics from 2015 to 2016. Dr. Pomerantz received his B.A. degree in Biochemistry from the Johns Hopkins University and his M.D. from the Johns Hopkins School of Medicine. Dr. Pomerantz received post-graduate training at the Massachusetts General Hospital, Harvard Medical School and M.I.T. Dr. Pomerantz is Board Certified in both Internal Medicine and Infectious Diseases. Dr. Pomerantz was Professor of Medicine, Biochemistry and Molecular Pharmacology, Chief of Infectious Diseases, and the Founding Director and Chair of the Institute for Human Virology and Biodefense at Thomas Jefferson University and Medical School. Dr. Pomerantz has developed nine drugs approved world-wide in important diseases, including HIV, HCV, and tuberculosis.

Oren Hershkovitz Ph.D, has served as the Company's Chief Executive Officer since November 2019. Prior to that, Dr. Hershkovitz served for nearly a decade in managerial and executive roles at PROLOR Biotech, Inc., including following its acquisition by OPKO and change in name to OPKO Biologics, Inc., acting as General Manager for more than 4.5 years. Dr. Hershkovitz successfully managed more than 70 employees and led manufacturing, non-clinical and clinical development for various Phase I, II and III programs, including for obesity, hemophilia and growth hormone deficiency. Dr. Hershkovitz earned his Ph.D. in immunology from the Ben Gurion University of the Negev with distinction.

Shachar Shlosberger, CPA., has served as the Company's Chief Financial Officer since 2016, bringing with her more than 12 years of financial experience in the hi-tech and biotechnology industries. Prior to her position at the Company, Ms. Shlosberger worked for four years at PROLOR Biotech, Inc. as Finance Director where she was responsible for the overall financial operations in Israel and the United States. Ms. Shlosberger is a Certified Public Accountant and holds a M.B.A. degree in Accounting and Business Administration from the College of Management in Israel.

Einat Galamidi, M.D., has served as the Company's Chief Medical Officer since February 2025. Dr. Galamidi joined Enlivex in February 2022 as Vice President of Medical, leading the Company's clinical development programs. Prior to that, Dr. Galamidi spent over 10 years at Gamida Cell Ltd., where she most recently served as Vice President of Clinical Development and led the clinical development for Omisirge®, a cell therapy for patients with hematologic malignancies planned for umbilical cord blood transplantation. Dr. Galamidi has over two decades of experience in early and late-stage drug development, with particular involvement in the clinical development of cellular therapies from first-in-man to registration studies for multiple clinical indications. Dr. Galamidi holds a M.Sc. degree in Cancer Research and Experimental Biology from the Hebrew University of Jerusalem and earned her M.D. from the same institution.

Abraham (Avri) Havron, Ph.D., has served as a director since 2014. Dr. Havron served as the Chief Executive Officer of PROLOR Biotech, Inc. from 2005 through 2013. Dr. Havron is a 44-year veteran of the biotechnology industry and was a member of the founding team and Director of Research and Development of Interpharm Laboratories (then, a subsidiary of Serono, later acquired by Merck) from 1980 to 1987, and headed the development of the multiple sclerosis drug REBIF, with current sales of more than Euro 1.0 billion annually. Dr. Havron served as Vice-President Manufacturing and Process-Development of BioTechnology General Ltd., from 1987 to 1999; and Vice President and Chief Technology Officer of Clal Biotechnology Industries Ltd. from 1999 to 2003. Dr. Havron's managerial responsibilities included the co-development of eight biopharmaceuticals currently in the market, including recombinant human growth hormone (BioTropin), recombinant Hepatitis B Vaccine (Bio-Hep-B), recombinant Beta Interferon (REBIF), recombinant human insulin, recombinant long-acting human growth hormone (Ngenla), a botanical burn debridement agent (Nexxobrid) and hyaluronic acid for ophthalmic and orthopedic applications. Dr. Havron earned his Ph.D. in Bio-Organic Chemistry from the Weizmann Institute of Science and served as a Research Fellow at Harvard Medical School, Department of Radiology. Dr. Havron served as a director of Kamada Ltd. (KMDA) from 2010 to 2018, and PamBio Ltd., a private biotech company, from 2016 to 2019. Dr. Havron also currently serves on the board of directors of CollPlant Biotechnologies Ltd. (CLGN), which position he has held since 2016.

Gili Hart, Ph.D., has served as a director since 2014. Dr. Hart is a biotech executive and since 2020, has served as the chief executive officer of SpilSense Ltd., a clinical stage company focused on transformative RNA-based treatments for pulmonary diseases. Dr. Hart has extensive experience in preclinical, clinical and global regulatory strategic planning, partnering with large-pharma, and financing. In addition, Dr. Hart brings broad experience in managing critical global programs ranging from discovery phase through Phase 3 clinical trials. Previously, Dr. Hart served as the chief executive officer of Mitoconix Bio (2017-2019), the General Manager of OPKO Biologics (2014 - 2017) and as VP of Pre-clinical and Clinical Pharmacology at PROLOR Biotech (2007 -2013). During 2005-2007, Dr. Hart was a Research Fellow at Yale University's School of Medicine. Dr. Hart holds Ph.D. and M.Sc. degrees, cum laude, from the Weizmann Institute of Science and a M.Sc. degree in Biotechnology Engineering, summa cum laude, from the Technion – Israel Institute of Technology. Dr. Hart has published numerous papers and patents; her scientific work is focused on autoimmunity diseases as well as on B and T cell maturation and migration that can directly affect inflammation and immune conditions.

Andew Singer has served as a director since April 2023. Mr. Singer is currently a corporate strategy consultant to biotech companies through his firm, Fika Bio Consulting Inc. Prior to that, Mr. Singer was a Managing Director at Credit Suisse from 2019 to 2023, ultimately named Head of West Coast Biotechnology Investment Banking. Before joining Credit Suisse, Mr. Singer was a Managing Director in Biotechnology Investment Banking at Wells Fargo from 2017 to 2019. Prior to joining Wells Fargo, Mr. Singer was Executive Vice President and Chief Financial Officer of Epizyme Inc., an oncology drug discovery and development company, from 2015 to 2017. At Epizyme, Mr. Singer's responsibilities included finance, business development, alliance management and corporate communications. From 2004 to 2015, Mr. Singer progressed from Vice President to Managing Director in the life sciences investment banking group of RBC Capital Markets. Mr. Singer holds a B.A. degree in East Asian studies from Yale University and M.B.A. degree from the Harvard Business School.

In February 2025, Dr. Brian Schwartz, who had served as a director since December 2020, passed away.

There are no arrangements or understandings with major shareholders, customers, suppliers or others pursuant to which any of our directors or members of senior management were selected as such. In addition, there are no family relationships among our executive officers and directors.

6.B. Compensation

The aggregate compensation of all directors and executive officers, including share-based compensation, for the year ended December 31, 2024, was $3,381,296. This amount includes $285,034 set aside or accrued to provide pension, severance, education fund, retirement, annual leave and recuperation or similar benefits or expenses, commonly provided by Israeli companies to their employees. This amount does not include any business travel and expenses reimbursed to office holders.

As of December 31, 2024, aggregate options to purchase 1,791,030 ordinary shares outstanding under our Global Share Incentive Plan (2014) (the "2014 Plan") and Global Share Incentive Plan (2019) (the "2019 Plan") and 843,441 restricted share units ("RSUs") outstanding under our 2019 Plan were granted to directors and executive officers. The options have a weighted average exercise price of $6.059 per share.

The aggregate compensation of our five most highly compensated directors and executive officers for the year ended December 31, 2024 (the "Covered Executives"), included cash compensation (salaries or fees, as applicable) of $1,019,758 and $285,034 in amounts set aside or accrued to provide pension, severance, education fund, retirement, annual leave and recuperation or similar benefits or expenses, commonly provided by Israeli companies to their employees (the "Benefits"). These aggregated amounts were allocated to the Covered Executives as follows: of the aggregate cash compensation, 45%, 24%, 16%, 13% and 2% was allocated to our Executive Chairman, Chief Executive Officer, Chief Medical Officer, Chief Financial Officer and Vice Chairman of the Board, respectively, and of the aggregate Benefits, 44%, 32% and 24% was allocated to our Chief Executive Officer, Chief Medical Officer and Chief Financial Officer, respectively. Our Executive Chairman and Vice Chairman of the Board did not receive Benefits in 2024. In addition, the Covered Executives received bonuses in 2024 in the aggregate amount of $830,881, which was allocated to the Covered Executives as follows: 79%, 14%, 5% and 2% to our Executive Chairman, Chief Executive Officer, Chief Medical Officer and Chief Financial Officer, respectively. Our Vice Chairman of the Board is not entitled to bonuses. We recorded a non-cash equity-based compensation expense in our financial statements for the year ended December 31, 2024, for options and RSUs granted to our Covered Executives, in the aggregate, of $1,046,341, which was allocated as follows: 69%, 12%, 10%, 5% and 3% to our Executive Chairman, Vice Chairman of the Board, Chief Executive Officer, Chief Medical Officer and Chief Financial Officer, respectively. For information regarding our accounting for share-based compensation arrangements, see Note 12 to our audited consolidated financial statements contained in this Annual Report on Form 20-F.

Employment and Consulting Agreements with Executive Officers and Directors

We have entered into written consulting and employment agreements with our Executive Chairman, Chief Executive Officer, Chief Financial Officer and Chief Medical Officer. All such agreements contain provisions regarding non-competition, confidentiality of information and assignment of inventions. The non-competition provisions apply for a period of 12 months following termination of employment of the respective officer. In addition, we are required to provide notice of between one and twelve months prior to terminating the employment of such executive officers other than in the case of a termination for cause.

Other than with respect to the Executive Chairman's consulting agreement, these agreements do not provide for benefits upon the termination of these executives' respective employment with us, other than payment of salary and benefits during the required notice period for termination of these agreements, which varies under these individual agreements.

With respect to the Executive Chairman's consulting agreement, if we terminate the Executive Chairman's Board service other than for cause, the Executive Chairman is entitled to the base retainer for the twelve-month period following the effective date of termination. The Executive Chairman is also entitled to certain other stock option payments upon such termination, and to certain benefits in the case the termination is due to long-term disability. Under the Executive Chairman's consulting agreement, as amended, the Executive Chairman is entitled to 3.33% of future gross proceeds actually received by the Company during the first five years from consummation of a commercial transaction or sale, as defined in the agreement. Such commissions will be paid once the aggregate consideration actually received by the Company in respect of such transactions will equal or exceed $20 million.

As approved by our shareholders at the 2021 annual general meeting of shareholders, for the year ended December 31, 2024, the non-executive directors (namely, all directors other than our Executive Chairman) were paid an annual fee of NIS 67,580 (approximately $18,530) and a per meeting fee of NIS 2,490 (approximately $682) until June 30, 2024, which thereafter increased to an annual fee of NIS 71,435(approximately $19,587) and a per meeting fee of NIS 3,113 (approximately $853) until June 30, 2025, which amounts will thereafter increase annually by 25% up to the maximum fixed amount payable from time to time by us under the Companies Regulations (Rules Regarding Compensation and Expense Reimbursement of External Directors), 2000.

Please see "Risk Factors—Risks Related to Our Business, Industry and Regulatory Requirements" for a further description of the enforceability of non-competition clauses. See "Related Party Transactions" below for additional information.

6.C. Board Practices

Board of Directors

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

Under our Amended and Restated Articles of Association, the Board must consist of at least five and not more than eleven directors. The Board of the Company is currently composed of five members, and includes Mr. Shai Novik, Dr. Abraham (Avri) Havron, Dr. Gili Hart, Dr. Roger Pomerantz and Mr. Andrew Singer. All of our directors were elected at our annual general meeting of shareholders held on November 8, 2024, and will serve until our next annual general meeting of shareholders (a "General Meeting") and until their respective successors are duly elected and qualified. Each of our directors shall be elected at an annual General Meeting and shall serve in his or her office until the next annual General Meeting, or until they cease to serve in their office in accordance with the provisions of our Amended and Restated Articles of Association or any law, whichever is the earlier. Vacancies on our board of directors, including vacancies resulting from there being fewer than the maximum number of directors permitted by Amended and Restated Articles of Association, may generally be filled by a vote of a simple majority of the directors then in office.

Under the Companies Law, the Board must determine the minimum number of directors who are required to have accounting and financial expertise. Under applicable regulations, a director with accounting and financial expertise is a director who, by reason of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements, sufficient to be able to thoroughly comprehend the financial statements of the company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, the Board must consider, among other things, the type and size of the company and the scope and complexity of its operations. The existing Board of the Company has determined that the Company requires one director with such expertise, and that both Mr. Shai Novik and Mr. Andrew Singer have such accounting and financial expertise.

None of our non-employee directors have any service contracts with the Company or any of our subsidiaries that provide for benefits upon termination of employment.

External Directors

Under the Companies Law, companies incorporated under the laws of the State of Israel that are publicly traded, including Israeli companies with shares listed on the Nasdaq, such as the Company, are required to appoint at least two external directors, who meet the qualifications requirements set forth in the Companies Law.

However, pursuant to the Israeli Companies Regulations (Relief for Companies Whose Shares are Registered for Trading Outside of Israel), 2000 (the "Relief Regulations"), if: (i) the company's shares are dual listed on the TASE and a foreign (non-Israeli) securities exchange which is referenced in the second or third addendum to the Israeli Securities Law, 1968, (the "Israeli Securities Law"), which include, among others, the NASDAQ Capital Market, or are listed solely on a foreign (non-Israeli) securities exchange; (ii) the company does not have a controlling shareholder (as such term is defined in the Companies Law); and (iii) the company satisfies the requirements of the laws in the foreign jurisdiction where the company's shares are listed, as they apply to companies incorporated in such jurisdiction, with respect to the appointment of independent directors and the composition of the audit committee and compensation committee, the board of directors of such company may elect to "opt out" of the Companies Law requirement to appoint external directors and related Companies Law rules concerning the composition of the audit committee and compensation committee (other than the gender diversification rule under the Companies Law, which requires the appointment of a director from the other gender if at the time of appointment of a director all members of the board of directors are of the same gender). In accordance with the Relief Regulations, our Board elected to "opt out" from such requirements of the Companies Law, such that following the Board's determination, we do not have external directors and must comply with U.S. laws (including the applicable Nasdaq Listing Rules) governing the appointment of independent directors and the composition of the audit committee and compensation committee applicable to domestic U.S. issuers.

Leadership Structure of the Board

In accordance with the Companies Law and the Amended and Restated Articles of Association, the Board is required to appoint one of its members to serve as Chairman of the Board. The Board has appointed Mr. Shai Novik to serve as Executive Chairman of the Board. In addition, the Board has appointed Dr. Roger Pomerantz to serve as Vice Chairman of the Board.

Role of Board in Risk Oversight Process

Risk assessment and oversight are an integral part of our governance and management processes. Our Board of Directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the Board of Directors at regular board meetings, including a description of steps taken by management to mitigate or eliminate such risks.

Board Committees

Audit Committee

The Companies Law requires public companies to appoint an audit committee. In accordance with the Relief Regulations described above, we elected to "opt out" from the Companies Law requirement to appoint external directors and related rules concerning the composition of the audit committee and compensation committee. Under such exemption, among other things, our audit committee is required to comply with the audit committee composition requirements under U.S. laws (including applicable Nasdaq Listing Rules and SEC rules) as applicable to U.S. domestic issuers.

Under the Nasdaq Listing Rules, the Company is required to maintain an audit committee consisting of at least three independent directors, all of whom are financially literate and one of whom has accounting or related financial management expertise, and none of whom has participated in the preparation of our or any of our subsidiaries' financial statements at any time during the prior three years. In addition, each member of the Audit Committee is required to be "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act.

The audit committee of the Company (the "Audit Committee") consists of three members, all of whom are independent under the Nasdaq Listing Rules and are "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act. The members of the Audit Committee are Dr. Avri Havron (as Chairman of the Audit Committee), Dr. Gili Hart and Mr. Andrew Singer. The Board of the Company has determined that Mr. Singer is an audit committee financial expert as defined by the SEC rules and has the requisite financial sophistication as defined by the Nasdaq Listing Rules. All the members of the Audit Committee meet the requirements for financial literacy under the applicable Nasdaq Listing Rules.

The Board of Directors has adopted an audit committee charter setting forth the responsibilities of the audit committee, which are consistent with the Companies Law, the SEC rules and the Nasdaq rules, which include:

- retaining and terminating our independent auditors, subject to ratification by the Board of Directors, and in the case of retention, to ratification by the shareholders;
- pre-approving audit and non-audit services to be provided by the independent auditors and related fees and terms;
- overseeing the accounting and financial reporting processes of our company and audits of our financial statements, the effectiveness of our internal control over financial reporting and making such reports as may be required of an audit committee under the rules and regulations promulgated under the Exchange Act;
- reviewing with management and our independent auditor our annual and quarterly financial statements prior to publication or filing with (or furnishing to, as the case may be) the SEC;
- reviewing on a continuing basis the activities, organizational structure and qualifications of our internal audit function;
- reviewing with our general counsel and/or external counsel, as deemed necessary, legal and regulatory matters that could have a material impact on the financial statements;
- identifying irregularities in our business administration, among other things, by consulting with the internal auditor or with the independent auditor, and suggesting corrective measures to the Board of Directors;
- reviewing policies and procedures with respect to transactions (other than transactions related to the compensation or terms of services) between the company and directors and officers or their affiliates, or transactions that are not in the ordinary course of the company's business and deciding whether to approve such acts and transactions, if required under the Companies Law;

- establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees; and

- determining whether certain related-party transactions are "material" or "extraordinary" for the purpose of the requisite approval procedures under the Companies Law and whether certain transactions with a controlling shareholder must be subject to a competitive procedure.

Compensation Committee

Under the Companies Law, the board of directors of Israeli publicly traded companies are required to appoint a compensation committee. In accordance with the Relief Regulations described above, we elected to "opt out" from the Companies Law requirement to appoint external directors and related rules concerning the composition of the audit committee and compensation committee. Under such exemption, among other things, our compensation committee is required to comply with the compensation committee composition requirements under U.S. laws (including applicable Nasdaq Listing Rules and SEC rules) as applicable to U.S. domestic issuers.

Under the Nasdaq Listing Rules, the Company is required to maintain a compensation committee consisting entirely of independent directors.

The compensation committee of the Company (the "Compensation Committee") consists of three members, Dr. Roger Pomerantz (as Chairman of the Compensation Committee), Dr. Avri Havron and Dr. Gili Hart, all of whom are independent under the Nasdaq Listing Rules.

The responsibilities of the compensation committee as set forth in the Companies Law include the following:

- To recommend to the Board of Directors as to a compensation policy for office holders of the company, as well as to recommend, once every three years, any extensions to a compensation policy that was adopted for a period of more than three years;

- To review the implementation of the compensation policy by the company, and periodically recommend to the Board of Directors as to any updates to the compensation policy which may be required;

- To approve transactions relating to terms of office and employment of certain company office holders, which require the approval of the compensation committee pursuant to the Companies Law; and

- To exempt, under certain circumstances, a transaction relating to terms of office and employment with our chief executive officer from the requirement of approval of the shareholders meeting.

An "office holder" is defined in the Companies Law as a chief executive officer (referred to in the Companies Law as a general manager), chief business manager, deputy chief executive officer, vice chief executive officer, any other person assuming the responsibilities of any of these positions regardless of that person's title, any other manager directly subordinate to the chief executive officer and a director.

The Board of Directors has adopted a compensation committee charter setting forth the responsibilities of the compensation committee, which are consistent with the Companies Law and the corporate governance rules of the Nasdaq and include among others:

- recommending to the Board of Directors for its approval a compensation policy in accordance with the requirements of the Companies Law, as well as other compensation policies, incentive-based compensation plans and equity-based compensation plans, and overseeing the development and implementation of such policies and recommending to the Board of Directors any amendments or modifications to such policies the compensation committee deems appropriate, including as required under the Companies Law;

- reviewing and approving the granting of options and/or other incentive awards to our chief executive officer and other executive officers, including reviewing and approving corporate goals and objectives relevant to the compensation of our chief executive officer and other executive officers;

- approving and exempting certain transactions regarding office holders' compensation pursuant to the Companies Law; and

- administering our equity-based compensation plans, including without limitation, approving the adoption of such plans, amending and interpreting such plans and the awards and agreements issued pursuant thereto, and making awards to eligible persons under the plans and determining the terms of such awards.

Compensation Policy

Under the Companies Law, following the compensation committee's recommendations, the board of directors is required to establish a compensation policy, which includes a framework for establishing the terms of office and employment of the office holders and guidelines with respect to the structure of the variable pay of office holders. Such guidelines are the basis for adequate balance between the components of compensation, which exists when a linkage is maintained between compensation and performance and the creation of value for shareholders in the Company, while maintaining the Company's ability to recruit and retain talented officeholders and incentivizing them to pursue the Company's objectives. In particular, an appropriate balance between the fixed component (base salary and additional benefits) and the variable component and capital compensation avoids placing an exaggerated emphasis on one component.

Under the Companies Law, a company's compensation policy shall be determined based on, and take into account, the following parameters:

- Advancement of the goals of the company, its working plan and its long term policy;

- The creation of proper incentives for the office holders while taking into consideration, among other things, the company's risk management policies;

- The company's size and nature of its operations;

- The contributions of the relevant office holders in achieving the goals of the company and profit in the long term in light of their positions;

- The education, skills, expertise and achievements of the relevant office holders;

- The role of the office holders, areas of their responsibilities and previous agreements with them;

- The correlation of the proposed compensation with the compensation of other employees of the company, and the effect of such differences in compensation on the employment relations in the company; and

- The long term performance of the office holder.

In addition, the compensation policy should take into account that in the event the compensation paid to office holders shall include variable components – it should address the ability of the board of directors to reduce the value of the variable component from time to time or to set a cap on the exercise value of convertible securities components that are not paid out in cash. Additionally, in the event that the terms of office and employment include grants or payments made upon termination – such grants should take into consideration the length of the term of office or period of employment, the terms of employment of the office holder during such period, the company's success during said period and the office holder's contribution to obtaining the company's goals and maximizing its profits as well as the circumstances and context of the termination.

In addition, the compensation policy must set forth standards and rules on the following issues: (a) with respect to variable components of compensation – (i) with the exception of office holders who report directly to the chief executive officer, basing the compensation on long term performance and measurable criteria (though a non-material portion of the variable components can be discretionary awards taking into account the contribution of the office holder to the company, in the amount of up to three month salaries of the relevant office holder on an annual basis); (ii) establishing the appropriate ratio between variable components and fixed components and placing a cap on such variable components (including a cap on the grant date value of convertible securities components that are not paid out in cash); (b) setting forth clawback rules requiring an office holder to return amounts paid in the event that it is later revealed that such amounts were paid on the basis of data which prove to be erroneous and resulted in a restatement of the company's financial statements; (c) determining minimum holding or vesting periods for equity based variable components of compensation, while taking into consideration appropriate long term incentives; and (d) setting a cap on grants or benefits paid upon termination.

The board of directors of a company is obligated to adopt a compensation policy after considering the recommendations of the compensation committee. The final adoption of the compensation committee is subject to the approval of the shareholders of the company by a certain special majority requirement, as set forth in the Companies Law, pursuant to which one of the following must be met:

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

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

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

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

Our current Compensation Policy was approved at the annual general meeting of our shareholders held in November 2024.

Nominating Committee

We rely on the exemption available to foreign private issuers under the Nasdaq Listing Rules and follow Israeli law and practice with regard to the process of nominating directors, in accordance with which our Board (or a committee thereof) is authorized to recommend to our shareholders director nominees for election.

In May 2022, our Board established a non-independent nominating committee (the "Nominating Committee"), whose role is (among other things) to identify and recommend director nominees for election by the shareholders, while considering the appropriate size and composition of the Board of Directors, the requirements applicable to all members of the Board of Directors and the criteria for the selection of new members of the Board of Directors. The Board, however, retains the power and authority to exercise the authority of the Nominating Committee at any time. The Nominating Committee currently consists of two members, Mr. Shai Novik (as Chairman of the Nominating Committee) and Dr. Gili Hart.

Internal auditor

Under the Companies Law, the Board of Directors of an Israeli public company must appoint an internal auditor recommended by the audit committee. Under the Companies Law, an internal auditor may not be:

- a person (or a relative of a person) who holds more than 5% of the Company's outstanding shares or voting rights;
- a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;
- an office holder (including a director) of the company (or a relative thereof); or
- a member of the company's independent accounting firm, or anyone on his or her behalf.

The role of the internal auditor is, among other things, to examine our compliance with applicable law and orderly business procedures. Alon Amit of Raveh Ravid Internal Audit Services Ltd. serves as our internal auditor.

6.D. Employees

As of December 31, 2024, the Company had 36 full time employees, of whom 28 employees are involved in product development and eight employees provide general and administrative services. All of these employees are located in Israel. In addition, the Company's former Chief Scientific and Medical Officer provides consulting services on a part-time basis pursuant to a consulting agreement.

None of the Company's employees are party to any collective bargaining agreements or represented by any labor unions. However, in Israel, the Company is subject to certain Israeli labor laws, regulations, rulings of Israeli labor courts and certain provisions of collective bargaining agreements that apply to its employees by virtue of extension orders issued by the Israel Ministry of Economy and which apply such agreement provisions to the Company's employees even though they are not part of a union that has signed a collective bargaining agreement. These labor laws and regulations primarily govern the length of the workday, minimum daily wages for professional workers, pension fund benefits for all employees, insurance for work-related accidents, procedures for dismissing employees, determination of severance pay and other conditions of employment. Israeli law generally requires severance pay, which may be funded by managers' insurance and/or a pension fund described below, upon the retirement or death of an employee or termination of employment without cause (as may be defined in the employment agreements). The payments to the managers' insurance and/or pension fund in respect of severance pay amount to approximately 8.33% of an employee's wages, in the aggregate. Furthermore, Israeli employees and employers are required to pay predetermined sums to the National Insurance Institute. Such amounts also include payments for national health insurance. The payments to the National Insurance Institute (including payments for healthcare insurance) are paid on a differential basis, such that with respect to the part of the employee's wage which is equal to up to 60% of the average wage in Israel, the employer is required to pay an amount equal to 3.55% of such part of the employee's wage and the employee is required to pay an amount equal to 3.50% of such part of the employee's wage, and for the remainder of the employee's wage up to the maximum wage amount on which payments to the National Insurance Institute are required to be paid, the employer is required to pay an amount equal to 7.60% of such part of the employee's wage and the employee is required to pay an amount equal to 12% of such part of the employee's wage. In addition, pursuant to the provisions of Section 14 to the Israeli Severance Pay Law, 1963 (the "Section 14 Arrangement"), the payment of monthly deposits by us into managers' insurance and/or pension fund are in respect of severance obligation to such employees. These funds provide a combination of savings plan, insurance and severance pay benefits to the employee, giving the employee a lump sum payment upon retirement and securing the severance pay or part of it, if legally entitled, upon termination of employment. Each employee contributes an aggregate amount equal to 6% of his or her base salary to such funds, and the Company contributes, in the aggregate, an additional 14.83% to 15.83% of the employee's base salary, with such amount including the 8.33% which is contributed as severance pay as noted above. The monthly contributions as mentioned above constitute the required payment for severance pay, and if the respective employment agreement includes the required provisions pursuant to the Section 14 Arrangement, the Company is not required to pay any additional sum upon termination of employment for the period during which the Sections 14 Arrangement applies. The Company generally provides its employees with benefits and working conditions above the required minimums. The Company has never experienced any employment-related work stoppages and believes its relationship with its employees is good.

All of the Company's employment agreements include employees' undertakings with respect to non-competition, confidentiality and the assignment to the Company of intellectual property rights developed in the course of employment. However, under current applicable Israeli labor laws, the Company may not be able to enforce (either in whole or in part) covenants not to compete and therefore may be unable to prevent its competitors from benefiting from the expertise of some of the Company's former employees.

6.E. Share ownership

For information regarding the beneficial ownership of the Company's ordinary shares by our directors and officers, see Item 7.A. "Major Shareholders and Related Party Transactions — Major Shareholders."

Equity Incentive Plans

In May 2014, we adopted the 2014 Plan. Following the adoption of the 2019 Plan, as described below, no additional awards may be granted under the 2014 Plan.

In June 2019, we adopted the 2019 Plan, under which all ordinary shares that remained available for future grant under all existing plans were reserved for issuance with respect to awards that may be granted under the 2019 Plan.

As of December 31, 2024, options to purchase an aggregate 2,898,015 ordinary shares were issued and outstanding under the 2014 Plan and the 2019 Plan and 1,234,572 RSUs were issued and outstanding under the 2019 Plan, and 2,121,494 ordinary shares remained available for future issuance under the 2019 Plan. Of such outstanding options, options to purchase an aggregate 2,315,048 ordinary shares were vested as of that date, with a weighted average exercise price of $5.46 per share.

The 2019 Plan is administered by our Board of Directors, which shall determine, subject to Israeli law, the grantees of awards and various terms of the grant. The 2019 Plan provides for granting options in compliance with Section 102 of the Israeli Income Tax Ordinance, 1961 (the "Israeli Tax Ordinance").

Options and RSUs granted under the 2019 Plan to Israeli employees have been granted under the capital gains track of Section 102 of the Israeli Tax Ordinance. Section 102 of the Israeli Tax Ordinance allows employees, directors and officers, who are not controlling shareholders, to receive favorable tax treatment for compensation, including in the form of options or RSUs. Our Israeli non-employee service providers and controlling shareholders may only be granted options or RSUs under Section 3(i) of the Israeli Tax Ordinance, which does not provide for similar tax benefits. Section 102 of the Israeli Tax Ordinance includes two alternatives for tax treatment involving the issuance of options, or RSUs or shares to a trustee for the benefit of the grantees and also includes an additional alternative for the issuance of options, RSUs or shares directly to the grantee (without a trustee). Section 102(b)(2) of the Israeli Tax Ordinance, the most favorable tax treatment for grantees, permits the issuance to a trustee under the "capital gains track." However, under this track we are not allowed to deduct an expense with respect to the issuance of the options or RSUs. In order to comply with the terms of the capital gains track, all options and RSUs granted under the 2014 and 2019 Plans pursuant and subject to the provisions of Section 102 of the Israeli Tax Ordinance, as well as the ordinary shares issued upon exercise of these options or vesting of the RSUs and other shares received subsequently following any realization of rights with respect to such options or RSUs, such as share dividends and share splits, must be granted to a trustee for the benefit of the relevant employee, director or officer and should be held by the trustee for at least two years after the date of the grant.

Options and RSUs granted under the 2019 Plan will generally vest over four years commencing on the date of grant, such that 25% vest after one year and thereafter, the options or RSUs vest in three equal annual installments (every 12 months), each equal to 25% of the shares subject to the option or RSU granted, over three years. Options that are not exercised within ten years from the grant date expire, unless otherwise determined by the Board of Directors or its designated committee, as applicable. In case of termination for reasons of disability or death, the grantee or his legal successor may exercise options that have vested prior to termination within a period of six to twelve months from the date of disability or death. If we terminate a grantee's employment or service for cause, all of the grantee's vested and unvested options and unvested RSUs will expire on the date of termination. If a grantee's employment or service is terminated for any other reason, the grantee may generally exercise his or her vested options within 90 days of the date of termination. Any expired or unvested options or RSUs return to the pool for reissuance.

In the event of a merger or consolidation of our company subsequent to which we shall no longer exist as a legal entity, or a sale of all, or substantially all, of our shares or assets or other transaction having a similar effect on us, then any outstanding option and RSU shall be assumed, or an equivalent option or RSU shall be substituted, or the right to receive consideration, by such successor corporation or an affiliate thereof or, in case the successor corporation refuses to assume or substitute the option, our Board of Directors or its designated committee may (a) provide the grantee with the opportunity to exercise the option as to all or part of the shares, vested or otherwise, and/or (b) determine that all or a portion of any outstanding option and RSU shall be canceled upon consummation of the transaction and the holders thereof will receive consideration, or no consideration; and/or (c) determine that an adjustment or interpretation of the terms of the awards shall be made to facilitate the transaction.

Copies of the 2014 Plan and the 2019 Plan are filed as exhibits to this Annual Report on Form 20-F.

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

None.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

7.A. Major Shareholders

The following table and the related notes present information with respect the beneficial ownership of the Company's ordinary shares as of March 31, 2025, by:

- each shareholder known by us to beneficially own more than 5% of the Company's outstanding ordinary shares;
- each director and executive officer of the Company; and
- all of the Company's directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. The percentage of ordinary shares beneficially owned is based on 23,849,935 ordinary shares issued and outstanding as of March 31, 2025.

Ordinary shares of the Company that may be acquired by an individual or group within 60 days of March 31, 2025, pursuant to the exercise of the Company's outstanding options or warrants or the vesting of outstanding RSUs, are deemed outstanding for the purposes of computing the percentage of ordinary shares beneficially owned by such individual or group, but are not deemed outstanding for purposes of computing the percentage of ordinary shares beneficially owned by any other individual or group shown in the table.

Beneficial Owner	Number of Ordinary Shares Beneficially Owned	Percentage of Ordinary Shares Beneficially Owned
The Company's 5% or Greater Shareholders (other than Directors and Executive Officers)		
Armistice Capital, LLC (1)	2,208,000	9.26%
Directors and Executive Officers		
Shai Novik (2)	1,882,242	7.57%
Roger Pomerantz (3)	75,620	*
Oren Hershkovitz (4)	222,046	*
Shachar Shlosberger (5)	25,831	*
Avri Havron (6)	236,342	*
Gili Hart (7)	73,476	*
Andrew Singer (8)	13,298	*
Einat Galamidi (9)	26,571	*
All directors and executive officers as a group (8 persons)	2,555,426	10.10%

* Less than 1%.

(1) Based on Amendment No. 1 to Schedule 13G filed with the SEC on February 14, 2025, which provides that Armistice Capital, LLC ("Armistice Capital") is the investment manager of Armistice Capital Master Fund Ltd. (the "Master Fund"), the direct holder of the Company's ordinary shares, and pursuant to an Investment Management Agreement, Armistice Capital exercises voting and investment power over the securities of the Company held by the Master Fund and thus, may be deemed to beneficially own the securities of the Company held by the Master Fund. Mr. Steven Boyd, as the managing member of Armistice Capital, may be deemed to beneficially own the securities of the Company held by the Master Fund. The Master Fund specifically disclaims beneficial ownership of the securities of the Company directly held by it by virtue of its inability to vote or dispose of such securities as a result of its Investment Management Agreement with Armistice Capital.

(2) Includes 1,023,467 ordinary shares underlying options currently exercisable or exercisable within 60 days from March 31, 2025, of which 132,979 options expire in December 2033 and have an exercise price of $2.69, 145,238 options expire in December 2033 and have an exercise price of $6.22, 250,000 options expire in May 2030 and have an exercise price of $3.66, 250,000 options expire in May 2031 and have an exercise price of $12.23, and 245,250 options expire in November 2032 and have an exercise price of $5.34.

(3) Includes 75,000 ordinary shares underlying options currently exercisable or exercisable within 60 days from March 31,2025, which expire in November 2032 and have an exercise price of $5.967.

(4) Includes 180,000 ordinary shares underlying options currently exercisable or exercisable within 60 days from March 31, 2025, of which 150,000options expire in December 2033 and have an exercise price of $8.19 and 30,000 options expire in November 2032 and have an exercise price of $5.34.

(5) Includes 938 RSUs that vest within 60 days from March 31, 2025 and 19,418ordinary shares underlying options currently exercisable or exercisable within 60 days from March 31, 2025, of which 1,937 options expire in December 31, 2033 and have an exercise price of $2.69, 1,452 options expire in December 31, 2033 and have an exercise price of $2.69, 1,452 options expire in December 31, 2033 and have an exercise price of $6.22, 1,452 options expire in December 31, 2033 and have an exercise price of $10.12, 5,000 options expire in March 2030 and have an exercise price of $4.68, 5,625 options expire in March 2032 and have an exercise price of $5.34. and 2,500 options expire in March 2034 and have an exercise price of $3.21.

(6) Includes 54,883 ordinary shares underlying options currently exercisable or exercisable within 60 days from March 31, 2025, of which 53,192 options expire in December 31, 2033 and have an exercise price of $2.69 and 1,691 options expire in November 2032 and have exercise price of $5.34.

(7) Includes 68,181 ordinary shares underlying options currently exercisable or exercisable within 60 days from March 2025, of which 66,490 expire in December 31, 2033 and have an exercise price of $2.69 and 1,691 options expire in November 2032 and have exercise price of $5.34.

(8) Includes 13,298 ordinary shares underlying options currently exercisable or exercisable within 60 days from March 2025, which expire in November 2033 and have an exercise price of $3.53.

(9) Includes 21,250 ordinary shares underlying options currently exercisable or exercisable within 60 days from March 2025, of which 18,750 options expire in March 2032 and have an exercise price of $5.34 and 2,500 options expire in March 2034 and have an exercise price of $3.21.

To our knowledge, other than as disclosed in the table above, our other filings with the SEC and this Annual Report on Form 20-F, there has been no significant change in the percentage ownership held by any major shareholder since January 1, 2022. None of our shareholders has different voting rights from other shareholders.

According to our transfer agent, as of March 31, 2025, there were 86 record holders of our ordinary shares, among whom are six U.S. resident shareholders of record (including Cede & Co., the nominee of the Depositary Trust Company, holding 91.98% of our outstanding ordinary shares as of such date). The number of record holders in the United States is not representative of the number of beneficial holders nor is it dispositive with respect to where such beneficial holders are resident because many of these ordinary shares are held by brokers or other nominees. None of our shareholders has different voting rights from other shareholders.

The Company is not directly or indirectly owned or controlled by another corporation, by any foreign government or by any natural or legal persons, severally or jointly.

We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

7.B. Related Party Transactions

Approval of Related Party Transactions under Israeli Law

Fiduciary duties of office holders

The Companies Law imposes a duty of care and a duty of loyalty on all office holders of a company. The duty of care of an office holder is based on the duty of care set forth in connection with the tort of negligence under the Israeli Torts Ordinance (New Version) 5728-1968. This duty of care requires an office holder to act with the degree of proficiency with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes a duty to use reasonable means, in light of the circumstances, to obtain:

- information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to these actions.

The duty of loyalty requires an office holder to act in good faith and for the benefit of a company, and includes the duty to:

- refrain from any act involving a conflict of interest between the performance of his or her duties in a company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the business of a company;
- refrain from exploiting any business opportunity of the company for the purpose of gaining a personal advantage for himself or herself or others; and
- disclose to the company any information or documents relating to a company's affairs which the office holder received as a result of his or her position as an office holder.

We may approve an act performed in breach of the duty of loyalty of an office holder provided that the office holder acted in good faith, the act or its approval does not harm the Company, and the office holder discloses his or her personal interest, as described below.

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

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

The term "personal interest" is defined under the Companies Law to include the personal interest of a person in an action or in the business of a company, including the personal interest of such person's relative or the interest of any corporation in which the person is an interested party, but excluding a personal interest stemming solely from the fact of holding shares in such company. A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the interest of the office holder with respect to his or her vote on behalf of the shareholder for whom he or she holds a proxy even if such shareholder itself has no personal interest in the approval of the matter. An office holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction.

Under the Companies Law, an extraordinary transaction which requires approval is defined as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on the company's profitability, assets or liabilities.

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

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

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

Compensation of directors and executive officers

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

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

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

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

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

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

Under the Companies Law, extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest, as well as regarding the terms of services provided by a controlling shareholder or his or her relative, directly or indirectly (including through a corporation controlled by a controlling shareholder), the terms of employment of a controlling shareholder or his or her relative who is employed by the company and who is not an office holder and the terms of service and employment, including exculpation, indemnification or insurance, of a controlling shareholder or his or her relative who is an office holder require the approval of each of (i) the audit committee or the compensation committee with respect to terms of service and employment by the company as an office holder, employee or service provider, (ii) the board of directors and (iii) the shareholders, in that order. In addition, the shareholder approval must fulfill one of the following requirements: (a) at least a majority of the shares held by shareholders who have no personal interest in the transaction and who are present and voting at the meeting on the matter are voted in favor of approving the transaction, excluding abstentions; or (b) the shares voted against the transaction by shareholders who have no personal interest in the transaction who are present and voting at the meeting represent no more than 2% of the voting rights in the company.

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

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors, relating to terms of service or employment, that would otherwise require approval of the shareholders may be exempt from shareholder approval upon certain determinations of the audit committee and board of directors.

Significant Private Placements

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

Certain Relationships and Related Party Transactions

The following is a summary description of the material terms of those transactions with related parties to which we are party, and which were in effect since the beginning of the year ended December 31, 2024.

Research Agreement with Prof. Dror Mevorach and Cell Generation (C-G) Ltd.

On May 12, 2019, we entered into a research agreement with Cell Generation (C-G) Ltd. ("C-G"), pursuant to which C-G will carry out cell collections from Apheresis site at facilities operated by C-G, employing the services of Prof. Dror Mevorach as the principal investigator (the "C-G Research Agreement"). Prof. Dror Mevorach served as our Chief Science& Medical Officer from 2009 until March 1, 2024. The C-G Research Agreement will expire on the earlier of: (i) the completion of the subject study according to the protocols provided therein and submission of all reports, case report forms and other documentation required thereunder, and (ii) the termination of the C-G Research Agreement by us or C-G pursuant to the terms of the C-G Research Agreement, which either party may do without cause. Upon entry into the C-G Research Agreement, we paid C-G a non-refundable advance in the amount of NIS 430,000, plus VAT, and we are obligated to pay C-G certain collection, screening and recruitment remuneration upon request. The C-G Research Agreement provides us with the option to acquire all of the outstanding shares of C-G, starting on the second anniversary of the C-G Research Agreement, at an exercise price that shall be defined in good faith by an appraiser acceptable to both parties.

Agreements with Directors and Officers

Employment and consulting agreements. We have entered into written consulting and employment agreements with our Executive Chairman, Chief Executive Officer, Chief Financial Officer and Chief Medical Officer. See Item 6.B. "Directors, Senior Management and Employees—Compensation—Employment and Consulting Agreements with Executive Officers and Directors."

Indemnification, Exculpation and Insurance. Our Amended and Restated Articles of Association permit us to exculpate, indemnify and insure each of our directors and officers to the fullest extent permitted by the Companies Law. We have entered into agreements with each of our directors and officers, exculpating them, to the fullest extent permitted by the Companies Law, from liability for monetary or other damages due to, or arising or resulting from, a breach of the duty of care to the Company and undertaking to indemnify them to the fullest extent permitted by Israeli law, including with respect to liabilities resulting from certain acts performed by such directors and officers in their capacity as an office holder of the Company, our subsidiaries or affiliates. The indemnification is limited both in terms of amount and coverage. In addition, we have obtained directors' and officers' liability insurance with maximum coverage of $5 million in the aggregate for the benefit of the Company and our officers and directors. Such directors' and officers' liability insurance contains certain standard exclusions.

Options and restricted share units. We have granted options to purchase our ordinary shares and RSUs to our executive officers and directors. We describe our equity incentive plans under Item 6.E. "Directors, Senior Management and Employees—Share ownership—Equity Incentive Plans."

7.C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

8.A. Consolidated Statements and Other Financial Information

Financial Statements

See Item 18 "Financial Statements."

Legal Proceedings

From time to time, we are involved in various routine legal proceedings incidental to the ordinary course of our business. We do not currently believe that the outcome of these legal proceedings has had in the recent past, or will have (with respect to any pending proceeding), significant effects on our financial position or profitability. Any future litigation may result in substantial costs and be a distraction to management. No assurance can be given that future litigation will not have a material adverse effect on our financial position. For an additional discussion of certain risks associated with legal proceedings, see Item 3.D. "Risk Factors."

Dividends

We have never paid any cash dividends on our ordinary shares and do not anticipate paying any cash dividends for the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our Board of Directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant.

The Companies Law imposes restrictions on our ability to declare and pay dividends. See Exhibit 2.1 to this Annual Report on Form 20-F under "Rights of Our Ordinary Shares—Dividend and Liquidation Rights" for additional information.

Payment of dividends may also be subject to Israeli withholding taxes. See Item 10.E. "Additional Information—Taxation— Israeli Taxation Considerations" below for additional information.

8.B. Significant changes

Except as disclosed elsewhere in this Annual Report on Form 20-F, there have been no other significant changes since December 31, 2024, until the date of the filing of this Annual Report on Form 20-F.

ITEM 9. THE OFFER AND LISTING

9.A. Offer and Listing Details

Not applicable.

9.B. Plan of Distribution

Not applicable.

9.C. Market for Ordinary Shares

Our ordinary shares are listed on the Nasdaq Capital Market under the symbol "ENLV" and on the Tel Aviv Stock Exchange under the symbol "ENLV."

9.D. Selling Shareholders

Not applicable.

9.E. Dilution

Not applicable.

9.F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

10.A. Share Capital

Not applicable.

10.B. Articles of Association

A copy of our Amended and Restated Articles of Association is attached as Exhibit 1.1 to this Annual Report on Form 20-F. Other than as set forth below, the information called for by this Item is attached as Exhibit 2.1 to this Annual Report on Form 20-F and is incorporated by reference into this Annual Report on Form 20-F.

Securities Register

We are registered with the Israeli Registrar of Companies. Our registration number is 51-471648-9. Our Amended and Restated Articles of Association provide that we may engage in any type of lawful business.

Board of Directors

See Item 7.B. "Major Shareholders and Related Party Transactions — Related Party Transactions — Approval of Related Party Transactions under Israeli Law."

Borrowing Powers

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

Share Capital

Our authorized share capital is NIS 18,000,000 divided into 45,000,000 ordinary shares with a nominal value of NIS 0.40 each. Our ordinary shares may be certificated or uncertificated, subject to the Companies Law.

Shareholder Meetings

Pursuant to the Companies Law, annual general meetings are required to be held at least once in every calendar year (within a period of 15 months after the holding of the last preceding annual general meeting), and at such time and place as may be determined by the Board of Directors. At a general meeting, decisions shall be adopted only on matters that were specified on the agenda.

The Companies Law provides that an extraordinary general meeting of shareholders may be called by the Board of Directors as it deems fit. In addition, the Board is required to convene an extraordinary general meeting of shareholders upon the written request of (i) two or more directors or 25% of the directors in office, or (ii) one or more shareholders holding, in the aggregate, at least (a) 5% of the issued share capital and 1% of the voting rights; or (b) 5% of the voting rights of the company.

Shareholders entitled to participate and vote at our general meetings are the shareholders of record on a date to be determined by the Board of Directors, which, according to the Relief Regulations, as a company dual listed on the TASE and the Nasdaq, may be between 4 and 60 days prior to the date of the meeting.

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

10.C. Material Contracts

We have not entered into any material contract within the two years prior to the date of this Annual Report on Form 20-F, other than contracts entered into in the ordinary course of business, or as otherwise described elsewhere in this Annual Report on Form 20-F.

10.D. Exchange Controls

There are currently no Israeli currency control restrictions on payments of dividends or other distributions with respect to our ordinary shares or the proceeds from the sale of our ordinary shares, except for the obligation of Israeli residents to file reports with the Bank of Israel regarding certain transactions. However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

Non-residents of Israel who purchase our securities with non-Israeli currency will be able to repatriate dividends (if any), liquidation distributions and the proceeds of any sale of such securities, into non-Israeli currencies at the rate of exchange prevailing at the time of repatriation, provided that any applicable Israeli taxes have been paid (or withheld) on such amounts.

Neither our Amended and Restated Articles of Association nor the laws of the State of Israel restrict in any way the ownership or voting of our ordinary shares by non-residents of Israel, except with respect to citizens of countries that are in a state of war with Israel.

10.E. Taxation

The following is a summary of the current tax structure, which is applicable to companies in Israel, with special reference to its effect on us. The following also contains a discussion of material Israeli and U.S. tax consequences to persons purchasing our ordinary shares. To the extent that the discussion is based on new tax legislation, which has yet to be subject to judicial or administrative interpretation, there can be no assurance that the views expressed in the discussion will accord with any such interpretation in the future. The discussion is not intended and should not be construed as legal or professional tax advice and is not exhaustive of all possible tax considerations.

The following summary is included herein as general information only and is not intended as a substitute for careful tax planning. Accordingly, each investor should consult his or her own tax advisor as to the particular tax consequences to such investor of the purchase, ownership or sale of an ordinary share, including the effect of applicable state, local, foreign or other tax laws and possible changes in tax laws.

Israeli Taxation Considerations

THE FOLLOWING IS A SUMMARY OF THE MATERIAL ISRAELI INCOME TAX LAWS APPLICABLE TO US. THIS SECTION ALSO CONTAINS A DISCUSSION OF MATERIAL ISRAELI INCOME TAX CONSEQUENCES CONCERNING THE OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES. THIS SUMMARY DOES NOT DISCUSS ALL THE ASPECTS OF ISRAELI INCOME TAX LAW THAT MAY BE RELEVANT TO A PARTICULAR INVESTOR IN LIGHT OF HIS OR HER PERSONAL INVESTMENT CIRCUMSTANCES OR TO SOME TYPES OF INVESTORS SUBJECT TO SPECIAL TREATMENT UNDER ISRAELI LAW. EXAMPLES OF THIS KIND OF INVESTOR INCLUDE RESIDENTS OF ISRAEL OR TRADERS IN SECURITIES WHO ARE SUBJECT TO SPECIAL TAX REGIMES NOT COVERED IN THIS DISCUSSION. TO THE EXTENT THAT THE DISCUSSION IS BASED ON NEW TAX LEGISLATION THAT HAS NOT YET BEEN SUBJECT TO JUDICIAL OR ADMINISTRATIVE INTERPRETATION, WE CANNOT ASSURE YOU THAT THE APPROPRIATE TAX AUTHORITIES OR THE COURTS WILL ACCEPT THE VIEWS EXPRESSED IN THIS DISCUSSION. THIS SUMMARY IS BASED ON LAWS AND REGULATIONS IN EFFECT AS OF THE DATE OF THIS ANNUAL REPORT AND DOES NOT TAKE INTO ACCOUNT POSSIBLE FUTURE AMENDMENTS WHICH MAY BE UNDER CONSIDERATION.

General Corporate Tax Structure in Israel

Israeli resident companies, such as us, are generally subject to the standard corporate tax on their taxable income, at the rate of 23% since 2018.

Capital gains derived by an Israeli resident company are generally subject to tax at the same rate as the prevailing corporate tax rate. Under Israeli tax legislation, a corporation will be considered as an "Israeli Resident" if it meets one of the following: (a) it was incorporated in Israel; or (b) its business is managed and controlled from Israel.

Taxation of Israeli Shareholders

Taxation of Israeli Individual Shareholders on Receipt of Dividends

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

A "substantial shareholder" is generally a person who alone, or together with his relative or another person who collaborates with such shareholder on a regular basis, holds, directly or indirectly, at least 10% of any of the "means of control" of the corporation. "Means of control" generally include the right to vote in a General Meeting of shareholders, the right to receive profits, the right to nominate a director or an officer, the right to receive assets upon liquidation (after settling the debts), or the right to instruct someone who holds any of the aforesaid rights regarding the manner in which he or she is to exercise such right(s), and whether by virtue of shares, rights to shares or other rights, or in any other manner, including by means of voting agreements or trusteeship agreements.

The term "Israeli Resident" for individuals is generally defined under the Israeli Tax Ordinance as an individual whose center of life is in Israel. According to the Israeli Tax Ordinance, in order to determine the center of life of an individual, account will be taken of the individual's family, economic and social connections, including: (a) the place of the individual's permanent residence; (b) the place of residence of the individual and his family; (c) the place of the individual's regular or permanent place of business or the place of his permanent employment; (d) place of the individual's active and substantial economic interests; (e) place of the individual's activities in organizations, associations and other institutions. The center of life of an individual will be presumed to be in Israel if: (a) the individual was present in Israel for 183 days or more in the tax year; or (b) the individual was present in Israel for 30 days or more in the tax year, and the total period of the individual's presence in Israel in that tax year and the two previous tax years is 425 days or more. The presumption in this paragraph may be rebutted either by the individual or by the assessing officer.

Regardless of whether shareholders may be liable for Israeli income tax on dividend distributions, the payment of the dividend may be subject to withholding of Israeli tax at source. Payers of dividends on our shares, including an Israeli stockbroker effectuating the transaction or the financial institution through which the shares are held, are required, subject to any of the foregoing exemptions, reduced tax rates and the demonstration of a shareholder of his, her or its foreign residency, to withhold taxes upon the distribution of dividends at a rate of 25%, provided that the shares are registered with a nominee company.

Taxation of Israeli Resident Corporations on Receipt of Dividends

Israeli resident corporations are generally exempt from Israeli corporate income tax with respect to dividends paid on our ordinary shares.

Taxation of Israeli Resident Shareholders on Capital Gains Taxes

The income tax rate applicable to real capital gain derived by an Israeli individual from the sale of shares which had been purchased after January 1, 2012, whether listed on a stock exchange or not, is 25%. However, if such shareholder is considered a "substantial shareholder" (as defined above) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30% in respect of the real capital gains derived from the sale of shares issued by the company in which he or she is a "substantial shareholder".

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

Moreover, capital gains derived by a shareholder who is a dealer or trader in securities, or to whom such income is otherwise taxable as ordinary business income, are taxed in Israel at ordinary marginal income tax rates (currently, up to 47% for individuals (not including excess tax, social security and health tax) and 23% for Israeli resident corporations).

Taxation of Non-Israeli Shareholders

Taxation of Non-Israeli Shareholders on Receipt of Dividends

Non-Israeli residents (corporations or individuals) are generally subject to Israeli income tax on the receipt of dividends paid on our shares at the rate of 25% (or 30%, if such non-Israeli resident is a "substantial shareholder" at the time receiving the dividend or on any date in the 12 months preceding such date), which tax will be withheld at source, unless a tax certificate is obtained from the Israeli Tax Authority authorizing withholding-exempt remittances or a reduced rate of tax pursuant to an applicable tax treaty.

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

For example, under the Convention Between the Government of the United States of America and the Government of Israel with Respect to Taxes on Income, as amended (the "Treaty"), Israeli withholding tax on dividends paid to a U.S. resident for treaty purposes may not, in general, exceed 25%, or 15% in the case of dividends paid out of the profits of an approved enterprise under the Israeli Law for the Encouragement of Capital Investments, 1959, subject to certain conditions. Where the recipient is a U.S. corporation owning 10% or more of the outstanding shares of the voting stock of the paying corporation during the part of the paying corporation's taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any) and not more than 25% of the gross income of the paying corporation for such prior taxable year (if any) consists certain interest or dividends, the Israeli tax withheld may not exceed 12.5%, subject to certain conditions.

As detailed above, regardless of whether shareholders may be liable for Israeli income tax on dividend distributions, the payment of the dividend may be subject to withholding of Israeli tax at source. Shareholders may be required to demonstrate that they are exempt from tax on their dividends in order to avoid withholding tax at source.

Taxation of Non-Israeli Shareholders on Capital Gains Taxes

Non-Israeli resident shareholders are generally exempt from Israeli capital gains tax on any gains derived from the sale, exchange or disposition of our ordinary shares, provided that such shareholders did not acquire their ordinary shares prior to our initial public offering on the TASE and such gains were not derived from a permanent establishment or business activity of such shareholders in Israel and if additional conditions are met. However, non-Israeli corporations will not be entitled to the foregoing exemptions if an Israeli resident (i) has a controlling interest of 25% or more in such non-Israeli corporation or (ii) is the beneficiary of or is entitled to 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly.

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

Regardless of whether shareholders may be liable for Israeli income tax on the sale of our ordinary shares, the payment of the consideration may be subject to withholding of Israeli tax at the source. Accordingly, shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding tax at source at the time of sale.

Estate and gift tax

Currently, Israeli law does not impose estate or gift taxes.

Excess Tax

Individual holders who are subject to tax in Israel (whether any such individual is an Israeli resident or non-Israeli resident) and who have taxable income that exceeds a certain threshold in a tax year (NIS 698,280 for 2023, NIS 721,560 for 2024 and 2025), will be subject to an additional tax, at the rate of 3% on any taxable income prior to January 1, 2025, and commencing January 1, 2025, at the rate of 3% on active taxable income and 5% on passive taxable income. For this purpose, passive taxable income includes taxable capital gains from the sale of securities and taxable income from interest and dividends, subject to the provisions of an applicable double tax treaty.

United States Federal Income Tax Consequences

THE FOLLOWING SUMMARY IS INCLUDED HEREIN FOR GENERAL INFORMATION AND IS NOT INTENDED TO BE, AND SHOULD NOT BE CONSIDERED TO BE, LEGAL OR TAX ADVICE. EACH U.S. HOLDER SHOULD CONSULT WITH HIS OR HER OWN TAX ADVISOR AS TO THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND SALE OF ORDINARY SHARES, INCLUDING THE EFFECTS OF APPLICABLE STATE, LOCAL, FOREIGN OR OTHER TAX LAWS AND POSSIBLE CHANGES IN THE TAX LAWS.

U.S. Federal Income Taxation

Subject to the limitations described in the next paragraph, the following discussion summarizes the material U.S. federal income tax consequences to a "U.S. Holder" arising from the purchase, ownership and sale of the ordinary shares. For this purpose, a "U.S. Holder" is a holder of ordinary shares that is the beneficial owner of such shares for U.S. federal income tax purposes and: (1) an individual citizen or resident of the United States, including an alien individual who is a lawful permanent resident of the United States or meets the substantial presence residency test under U.S. federal income tax laws; (2) a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) or a partnership (other than a partnership that is not treated as a U.S. person under any applicable U.S. Treasury Regulations) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia; (3) an estate, the income of which is subject to U.S. federal income tax regardless of source; (4) a trust if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust; (5) a trust that has a valid election in effect to be treated as a U.S. person to the extent provided in U.S. Treasury Regulations; or (6) any person otherwise subject to U.S. federal income tax on a net income basis in respect of the ordinary shares, if such status as a U.S. Holder is not overridden pursuant to the provisions of an applicable tax treaty.

This summary is for general information purposes only and does not purport to be a comprehensive description of all of the U.S. federal income tax considerations that may be relevant to a decision to purchase or hold our ordinary shares. This summary generally considers only U.S. Holders that will own our ordinary shares as capital assets. Except as explicitly discussed below, this summary does not consider the U.S. federal tax consequences to a person that is not a U.S. Holder, nor does it describe the rules applicable to determine a taxpayer's status as a U.S. Holder. This summary is based on the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), final, temporary and proposed U.S. Treasury Regulations promulgated thereunder, administrative and judicial interpretations thereof, and the Treaty, all as in effect as of the date hereof and all of which are subject to change, possibly on a retroactive basis, and all of which are open to differing interpretations. We will not seek a ruling from the U.S. Internal Revenue Service, or the IRS, with regard to the U.S. federal income tax treatment of an investment in our ordinary shares by U.S. Holders and, therefore, can provide no assurances that the IRS will agree with the conclusions set forth below.

This discussion does not address all of the aspects of U.S. federal income taxation that may be relevant to a particular shareholder based on such shareholder's particular circumstances and in particular does not discuss any estate, gift, generation-skipping, transfer, state, local or foreign tax considerations. In addition, this discussion does not address the U.S. federal income tax treatment of a U.S. Holder who is subject to special tax rules, including any U.S. Holder who is: (1) a bank, life insurance company, regulated investment company, or other financial institution or "financial services entity;" (2) a broker or dealer in securities, commodities, or foreign currency; (3) a person who acquired our ordinary shares in connection with employment or other performance of services; (4) a U.S. Holder that is subject to the U.S. alternative minimum tax; (5) a U.S. Holder that holds our ordinary shares as a hedge or as part of a hedging, straddle, conversion or constructive sale transaction or other risk-reduction transaction for U.S. federal income tax purposes; (6) a tax-exempt entity, qualified retirement plans, individual retirement accounts or other tax deferred accounts; (7) real estate investment trusts; (8) a U.S. Holder that expatriates out of the United States or a former long-term resident of the United States; (9) a person having a functional currency other than the U.S. dollar; (10) persons subject to special tax accounting rules under section 451(b) of the Code; (11) persons that generally mark their securities to market for U.S. federal income tax purposes; or (12) U.S. Holders that hold our ordinary shares in connection with a trade or business conducted outside the United States. This discussion does not address the U.S. federal income tax treatment of a U.S. Holder that owns, directly or constructively, at any time, ordinary shares representing 10% or more of the voting power or value of our shares. Additionally, the U.S. federal income tax treatment of persons who hold ordinary shares through a partnership or other pass-through entity are not considered.

You are encouraged to consult your own tax advisor with respect to the specific U.S. federal and state income tax consequences to you of purchasing, holding or disposing of our ordinary shares, including the effects of applicable state, local, foreign or other tax laws and possible changes in the tax laws.

Distributions on Ordinary Shares

The entire discussion in this section is subject to the discussion under the heading "Passive Foreign Investment Companies" below.

A U.S. Holder will generally be required to include in gross income as dividend income the amount of any distribution paid on ordinary shares (including the amount of any Israeli tax withheld on the date of the distribution), to the extent that such distribution does not exceed our current and accumulated earnings and profits, as determined for U.S. federal income tax purposes. The amount of a distribution that exceeds our earnings and profits will be treated first as a non-taxable return of capital, reducing the U.S. Holder's tax basis for the ordinary shares to the extent thereof, and then capital gain. Because we do not maintain calculations of our earnings and profits in accordance with U.S. federal income tax principles, U.S. Holders should expect that any distribution by us with respect to our ordinary shares will be reported to them as dividend income. Corporate holders generally will not be allowed a deduction for dividends received. For noncorporate U.S. Holders whose total adjusted income exceeds certain income thresholds, the maximum federal income tax rate for "qualified dividend income" and long-term capital gains is generally 20%, and for noncorporate U.S. Holders, whose total adjusted income does not exceed such thresholds, the maximum federal income tax rate for "qualified dividend income" and long-term capital gains is generally 15%. For this purpose, "qualified dividend income" includes, among other things, dividends received from a "qualified foreign corporation." A "qualified foreign corporation" is a corporation that is entitled to the benefits of a comprehensive tax treaty with the United States which includes an exchange of information program. The IRS has stated that the Israel/U.S. Tax Treaty satisfies this requirement and we believe we are eligible for the benefits of that treaty.

In addition, our dividends will be qualified dividend income if our ordinary shares are readily tradable on Nasdaq or another established securities market in the United States. Dividends will not qualify for the preferential rate if we are treated, in the year the dividend is paid or in the prior year, as a PFIC. As described in the section below entitled "Passive Foreign Investment Companies," if we were a PFIC in a year while a U.S. Holder held our ordinary shares, such ordinary shares remain an interest in a PFIC for all future years. The IRS takes the position that such rule will apply for purposes of determining whether the ordinary shares are an interest in a PFIC in the year a dividend is paid or in the prior year, even if we do not satisfy the tests to be a PFIC in either of those years. A U.S. Holder will not be entitled to the preferential rate: (1) if the U.S. Holder has not held our ordinary shares or ADRs for at least 61 days of the 121 day period beginning on the date which is 60 days before the ex-dividend date, or (2) to the extent the U.S. Holder is under an obligation to make related payments on substantially similar property. Any days during which the U.S. Holder has diminished its risk of loss on our ordinary shares are not counted towards meeting the 61-day holding period. Finally, U.S. Holders who elect to treat the dividend income as "investment income" pursuant to Code section 163(d)(4) will not be eligible for the preferential rate of taxation.

The amount of a distribution with respect to our ordinary shares will be measured by the amount of the fair market value of any property distributed, and for U.S. federal income tax purposes, the amount of any Israeli taxes withheld therefrom. See discussion above under "Israeli Tax Considerations." Cash distributions paid by us in NIS will be included in the income of U.S. Holders at a U.S. dollar amount based upon the spot rate of exchange in effect on the date the dividend is includible in the income of the U.S. Holder, and U.S. Holders will have a tax basis in such NIS for U.S. federal income tax purposes equal to such U.S. dollar value. If the U.S. Holder subsequently converts the NIS, any subsequent gain or loss in respect of such NIS arising from exchange rate fluctuations will be U.S. source ordinary income or loss.

Distributions paid by us will generally be foreign source income for U.S. foreign tax credit purposes and will generally constitute "passive category income". Subject to certain conditions and limitations, U.S. Holders may elect to claim a foreign tax credit against their U.S. income tax liability for Israeli income tax withheld from distributions received in respect of the ordinary shares. In general, these rules limit the amount allowable as a foreign tax credit in any year to the amount of regular U.S. tax for the year attributable to foreign source taxable income. This limitation on the use of foreign tax credits generally will not apply to an electing individual U.S. Holder whose creditable foreign taxes during the year do not exceed $300, or $600 for joint filers, if such individual's gross income for the taxable year from non-U.S. sources consists solely of certain passive income. A U.S. Holder will be denied a foreign tax credit with respect to Israeli income tax withheld from dividends received with respect to the ordinary shares if such U.S. Holder has not held the ordinary shares for at least 16 days out of the 31-day period beginning on the date that is 15 days before the ex-dividend date or to the extent that such U.S. Holder is under an obligation to make certain related payments with respect to substantially similar or related property. Any day during which a U.S. Holder has substantially diminished his or her risk of loss with respect to the ordinary shares will not count toward meeting the 16-day holding period. A U.S. Holder will also be denied a foreign tax credit if the U.S. Holder holds the ordinary shares in an arrangement classified as a "structured passive investment arrangement" (as defined in the U.S. Treasury Regulations). The rules relating to the determination of the U.S. foreign tax credit are complex. For example, U.S. Treasury Regulations provide that, in the absence of an election to apply the benefits of an applicable income tax treaty, in order for foreign income taxes to be creditable the relevant foreign income tax rules must be consistent with certain U.S. federal income tax principles, and we have not determined whether the Israeli income tax system meets this requirement. U.S. Holders should consult with their own tax advisors to determine whether, and to what extent, they are entitled to such credit. U.S. Holders that do not elect to claim a foreign tax credit may instead claim a deduction for Israeli income taxes withheld, provided such U.S. Holders itemize their deductions.

Disposition of Shares

The entire discussion in this section is subject to the discussion under the heading "Passive Foreign Investment Companies" below.

Upon the sale, exchange or other taxable disposition of our ordinary shares, a U.S. Holder will generally recognize capital gain or loss in an amount equal to the difference between such U.S. Holder's tax basis in the ordinary shares and the amount realized on the disposition of such ordinary shares (or its U.S. dollar equivalent determined by reference to the spot rate of exchange on the date of disposition, if the amount realized is denominated in a foreign currency). The gain or loss realized on the sale or exchange or other taxable disposition of ordinary shares will be long-term capital gain or loss if the United States Holder has a holding period of more than one year at the time of the disposition.

In general, gain realized by a U.S. Holder on a sale, exchange or other disposition of ordinary shares will generally be treated as U.S. source income for U.S. foreign tax credit purposes. A loss realized by a U.S. Holder on the sale, exchange or other disposition of ordinary shares is generally allocated to U.S. source income. However, U.S. Treasury Regulations require such loss to be allocated to foreign source income to the extent specified dividends were received by the taxpayer within the 24-month period preceding the date on which the taxpayer recognized the loss.

The deductibility of a loss realized on the sale, exchange or other disposition of ordinary shares is subject to limitations.

Tax on Net Investment Income

U.S. Holders who are individuals, estates or trusts will generally be required to pay a 3.8% tax on their net investment income (including dividends on and gains from the sale or other disposition of our ordinary shares), or in the case of estates and trusts on their net investment income that is not distributed. In each case, the 3.8% Medicare tax applies only to the extent the U.S. Holder's total adjusted income exceeds applicable thresholds.

Passive Foreign Investment Companies

Special U.S. federal income tax laws apply to a U.S. Holder who owns shares of a corporation that was (at any time during the U.S. Holder's holding period) a PFIC. We would be treated as a PFIC for U.S. federal income tax purposes for any tax year if, in such tax year, either:

- 75% or more of our gross income (including our pro rata share of gross income for any company, U.S. or foreign, in which we are considered to own 25% or more of the shares by value), in a taxable year is passive; or

- At least 50% of our assets, generally determined based upon the quarterly average of the value of our assets (including our pro rata share of the assets of any company in which we are considered to own 25% or more of the shares by value), in a taxable year are held for the production of, or produce, passive income

For this purpose, passive income generally consists of dividends, interest, certain rents and royalties, annuities and income from certain commodities transactions and from notional principal contracts. Passive assets are those assets that are held for production of passive income or do not produce income at all. Thus, cash will be a passive asset. Goodwill is an active asset to the extent attributable to activities that produce active income. The determination of whether a foreign corporation is a PFIC is a factual determination made annually and is therefore subject to change. If we are or become classified as a PFIC while a U.S. Holder holds shares of our stock, we generally will continue to be classified as a PFIC as to that U.S. Holder in later years even if we no longer satisfy the foregoing tests, unless the U.S. Holder makes a "deemed sale" election under the PFIC rules. If the "deemed sale" election is made, a U.S. Holder will be deemed to have sold the ordinary shares the U.S. Holder holds at their fair market value as of the date of such deemed sale and any gain from such deemed sale would be subject to the PFIC rules described below.

If we are a PFIC for any taxable year and any of our foreign subsidiaries is also a PFIC (any such subsidiary, a "Lower-Tier PFIC"), a U.S. Holder will be deemed to own a proportionate amount (by value) of the shares of each such Lower-Tier PFIC and will be subject to U.S. federal income tax according to the excess distribution rules described below on (i) certain distributions by any Lower-Tier PFIC and (ii) dispositions of shares of any Lower-Tier PFIC, in each case, as if the U.S. Holder held such shares directly, even though the U.S. holder will not receive any proceeds of those distributions or dispositions.

Excess Distribution Regime. If we are or become a PFIC, each U.S. Holder who has not elected to treat us as a qualified electing fund by making a "QEF election," or who has not elected to mark the shares to market (as discussed below), would, upon receipt of any "excess distribution" by us (generally, the excess of distributions received in a taxable year over 125% of the average of the annual distributions on our ordinary shares received during the preceding three taxable years or the U.S. Holder's holding period, whichever is shorter) and upon disposition of our ordinary shares at a gain, be liable to pay U.S. federal income tax at the then prevailing highest tax rates on ordinary income plus interest on such tax, as if the distribution or gain had been recognized ratably over the taxpayer's holding period for the ordinary shares, subject to any amounts of such distribution or gain that are allocated to the current year or to any taxable year before the first day of the first taxable year in which we became a PFIC which would be treated as ordinary income. The tax liability for amounts allocated to years prior to the year of disposition or the "excess distribution" will be payable generally without regard to offsets from deductions, losses and expenses. Gains (but not losses) realized on the sale of a U.S. Holder's ordinary shares cannot be treated as capital gains, even if the U.S. Holder holds the ordinary shares as capital assets. In addition, when shares of a PFIC are acquired by reason of death from a decedent that was a U.S. Holder, the tax basis of such shares would not receive a step-up to fair market value as of the date of the decedent's death, but instead would be equal to the decedent's basis if lower, unless all gain were recognized by the decedent. Indirect investments in a PFIC may also be subject to special U.S. federal income tax rules.

QEF Election. The PFIC taxation regime would not apply to a U.S. Holder who makes a QEF election for all taxable years that such U.S. Holder has held the ordinary shares while we are a PFIC, provided that we comply with specified reporting requirements. Instead, each U.S. Holder who has made such a QEF election is required for each taxable year that we are a PFIC to include in income such U.S. Holder's pro rata share of our ordinary earnings as ordinary income and such U.S. Holder's pro rata share of our net capital gains as long-term capital gain, regardless of whether we make any distributions of such earnings or gain. The QEF election is made on a shareholder-by-shareholder basis and generally may be revoked only with the consent of the IRS. In general, a QEF election is effective only if we make available certain required information, and we do not intend to provide such information; accordingly, a QEF election would not be available to U.S. Holders.

Mark-to-Market Regime. A U.S. Holder of PFIC shares which are traded on qualifying public markets, including the Nasdaq, can elect to mark the shares to market annually, recognizing as ordinary income or loss each year an amount equal to the difference as of the close of the taxable year between the fair market value of the PFIC shares and the U.S. Holder's adjusted tax basis in the PFIC shares, subject to the limitation discussed below with respect to losses. A U.S. Holder's adjusted tax basis in the PFIC shares will be increased to reflect any amounts included in income, and decreased to reflect any amounts deducted, as a result of a mark-to-market election. Any gain recognized on a disposition of ordinary shares in a taxable year in which we are a PFIC will be treated as ordinary income and any loss will be treated as ordinary loss (but only to the extent of the net amount of income previously included as a result of a mark-to-market election, with any excess treated as a capital loss). The PFIC interest charges do not apply to taxes arising from mark-to-market gains pursuant to such election. Losses are allowed only to the extent of net mark-to-market gain previously included income by the U.S. Holder under the election for prior taxable years. As with a QEF election, a mark-to-market election is made on a shareholder-by-shareholder basis, applies to all ordinary shares held or subsequently acquired by an electing U.S. Holder and can only be revoked with consent of the IRS (except to the extent the ordinary shares no longer constitute "marketable stock"). U.S. Holders should be aware that there is also no provision in the Code, the U.S. Treasury Regulations or other published authority that specifically provides that a mark-to-market election with respect to the stock of a publicly traded holding company effectively exempts stock of any Lower-Tier PFICs from the negative tax consequences arising from the "excess distribution" regime described above. Under current law, the mark-to-market election may be available to U.S. Holders because our ordinary shares are listed on the Nasdaq which should constitute a qualified exchange for this purpose, although there can be no assurance that the ordinary shares will be "regularly traded" for purposes of the mark-to-market election.

A U.S. Holder that owns (or is deemed to own) shares in a PFIC during any taxable year of the U.S. Holder generally is required to file an IRS Form 8621 with such U.S. Holder's U.S. federal income tax return if certain conditions are met and provide such other information as the IRS may require. Failure to file IRS Form 8621 for each applicable taxable year may result in substantial penalties and result in the U.S. Holder's taxable years being open to audit by the IRS until such forms are properly filed.

Based on the nature of our business, the projected composition of our income and the projected composition and estimated fair market values of our assets, we likely will be classified as a PFIC. In addition, we may have been a PFIC in prior years and may be a PFIC in the future. U.S. Holders who hold ordinary shares during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC, subject to exceptions for U.S. Holders described above. U.S. Holders are strongly urged to consult their tax advisors about the PFIC rules, including tax return filing requirements and the eligibility, manner, and consequences to them of making applicable elections under the PFIC rules.

Information Reporting and Withholding

A U.S. Holder may be subject to backup withholding (at a rate of 24% under current law) with respect to cash dividends and proceeds from a disposition of ordinary shares. In general, backup withholding will apply if a U.S. Holder fails to comply with specified identification procedures or if the U.S. Holder is otherwise subject to backup withholding. Backup withholding will not apply with respect to payments made to designated exempt recipients, such as corporations and tax-exempt organizations. Backup withholding is not an additional tax and may be claimed as a credit against the U.S. federal income tax liability of a U.S. Holder, provided that the required information is timely furnished to the IRS.

Foreign Asset Reporting

Certain U.S. Holders who are individuals (or certain specified entities) may be required to report information relating to an interest in the ordinary shares, subject to certain exceptions. U.S. Holders are urged to consult their tax advisors regarding the application of these and other reporting requirements that may apply to their ownership of ordinary shares.

Non-U.S. Holders of Ordinary Shares

Except as provided below, an individual, corporation, estate or trust that is not a U.S. Holder generally will not be subject to U.S. federal income or withholding tax on the payment of dividends on, and the proceeds from the disposition of, our ordinary shares.

A non-U.S. Holder may be subject to U.S. federal income or withholding tax on a dividend paid on our ordinary shares or the proceeds from the disposition of our ordinary shares if: (1) such item is effectively connected with the conduct by the non-U.S. Holder of a trade or business in the United States or, in the case of a non-U.S. Holder that is a resident of a country which has an income tax treaty with the United States, such item is attributable to a permanent establishment or, in the case of gain realized by an individual non-U.S. Holder, a fixed place of business in the United States; (2) in the case of a disposition of our ordinary shares, the individual non-U.S. Holder is present in the United States for 183 days or more in the taxable year of the sale and other specified conditions are met; or (3) the non-U.S. Holder is subject to U.S. federal income tax pursuant to the provisions of the U.S. tax law applicable to U.S. expatriates.

A non-U.S. Holder generally will be exempt from backup withholding but may be required to comply with certain certification and identification procedures in order to establish its eligibility for exemption.

The amount of any backup withholding from a payment to a non-U.S. Holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

10.F. Dividends and Paying Agents

Not applicable.

10.G. Statement by Experts

Not applicable.

10.H. Documents on Display

We are subject to certain of the information reporting requirements of the Exchange Act. As a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act prescribing 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, with respect to their purchase and sale of our ordinary shares. In addition, we are not required to file reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we are required to file with the SEC, within four months after the end of each fiscal year, an annual report on Form 20-F containing financial statements audited by an independent accounting firm. We publish unaudited interim financial information after the end of each quarter. We furnish this quarterly financial information to the SEC under cover of a Form 6-K.

The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants, like us, that file electronically with the SEC. The address of this website is http://www.sec.gov. Our SEC filings are also generally available to the public via the Israel Securities Authority's website at www.magna.isa.gov.il, and the TASE website at http://www.maya.tase.co.il.

10.I. Subsidiary information

Not applicable.

10.J. Annual Report to Security Holders

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position, results of operations or cash flows due to adverse changes in financial market prices and rates, including interest rates and foreign exchange rates, of financial instruments. Our market risk exposure is primarily a result of foreign currency exchange rates. As of December 31, 2024, $11,552,000 of our net assets (i.e., total assets net of total liabilities) were denominated in NIS while our functional currency is the U.S. dollar. Changes of 5% in the U.S. dollar against the NIS exchange rate would increase or decrease our expenses by $578,000.

Interest Rate Risk

We are currently not exposed to significant interest rate risk. Our only interest-bearing financial assets are principally cash and cash equivalents, restricted cash and short-term interest-bearing deposits, which are invested in major banks in Israel. Given the short-term nature of these investments, we do not believe our sensitivity with respect to interest rate fluctuations is significant. Therefore, the effect of an increase or decrease in interest rates would only have an immaterial effect on our financial results.

Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the NIS mainly against the U.S. dollar, and vice versa, because a considerable portion of our expenses are denominated in NIS. Our NIS expenses consist principally of payments made to employees, subcontractors and consultants for pre-clinical studies, clinical trials and other research and development activities. We anticipate that a sizable portion of our expenses will continue to be denominated in NIS. Our financial position, results of operations and cash flow are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates.

As of December 31, 2024, we were not engaged in foreign currency hedging transactions. In the future, we may enter into formal currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currency. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

Not applicable.

PART TWO

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

None.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2024. Based on such evaluation, those officers concluded that, as of December 31, 2024, our disclosure controls and procedures were effective in recording, processing, summarizing and reporting, on a timely basis, information required to be included in periodic filings under the Exchange Act and that such information is accumulated and communicated to management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based principally on the framework and criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission as of the end of the period covered by this report. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2024 at providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

(c) Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2024 has been audited by Yarel + Partners, our principal independent registered public accounting firm, as stated in their report that appears herein.

(d) Changes in Internal Control over Financial Reporting

During the year ended December 31, 2024, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15 (f) and 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our Board of Directors has determined that Mr. Andrew Singer, a member of our Audit Committee, is an audit committee financial expert, as defined under the rules under the Exchange Act, and is independent in accordance with applicable Exchange Act rules and the Nasdaq Listing Rules.

ITEM 16B. CODE OF ETHICS

We have adopted a written code of ethics that applies to our officers and employees, including our principal executive officer, principal financial officer, principal controller and persons performing similar functions as well as our directors. Our Code of Business Conduct and Ethics is posted on our website at https://www.enlivex.com. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report on Form 20-F and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC including the instructions to Item 16B of Form 20-F. We have not granted any waivers under our Code of Business Conduct and Ethics.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table provides information regarding fees paid by us to Yarel + Partners, our principal independent registered public accounting firm, for all services, including audit services, for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Audit fees [1]	$ 135,000	$ 126,000
Audit related fees [2]	-	13,000
Tax Fees [3]	17,000	17,000
All other fees	-	-
Total	$ 142,000	$ 156,000

(1) Includes professional services rendered in connection with the audit of our annual financial statements and the review of our interim financial statements.

(2) Audit-related fees relate to assurance and related services that traditionally are performed by the independent auditor including SEC filings, comfort letters, consents and comment letters in connection with regulatory filings.

(3) Includes fees related to professional services in connection with tax returns and other tax related services.

Pre-Approval of Auditors' Compensation

All of the audit services, audit-related services and tax services described in the table above were approved in advance by our Audit Committee in accordance with paragraph (c)(7)(i)(A) of Rule 2-01 of Regulation S-X and thereafter approved by our Board of Directors in accordance with Israeli law.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

On August 30, 2023, our Board of Directors authorized a share repurchase program for up to an aggregate amount of $1.5 million of the Company's outstanding ordinary shares, subject to court approval. On November 2, 2023, the Economic Department of the Tel Aviv District Court (the "Court") approved the Company's share repurchase program. The Court determined, in accordance with the Company's motion, that the repurchase of shares under the program, if any, must be completed within 45 days following the Court's approval. The Company did not purchase any shares under the share repurchase program, and the Company's Board of Directors approved the extension of the share repurchase program until June 30, 2024, subject to Court approval. On January 17, 2024, the Court approved the Company's motion to extend the share repurchase program until June 30, 2024, subject to compliance with applicable law.

During the year ended December 31, 2024, neither we nor any affiliated purchaser (as defined in the Exchange Act) purchased any of our ordinary shares, whether under the foregoing share repurchase program or otherwise.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

Our ordinary shares are listed on the Nasdaq Capital Market and accordingly, we are required to comply with Nasdaq Stock Market rules. Under those rules, as a "foreign private issuer" (as such term is defined in Rule 3b-4 under the Exchange Act), we may elect to follow certain corporate governance practices permitted under the Companies Law in lieu of compliance with corresponding corporate governance requirements otherwise imposed by the Nasdaq Stock Market rules for U.S. domestic issuers.

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

- *Distribution of periodic reports to shareholders*. As opposed to the Nasdaq Listing Rules, which require listed issuers to make such reports available to shareholders in one of a number of specific manners, Israeli law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports available through a public website. In addition to making such reports available on a public website, we currently make our audited financial statements available to our shareholders at our offices and will only mail such reports to shareholders upon request.

- *Quorum*. Under our Amended and Restated Articles of Association and as permitted under the Companies Law, a quorum for any meeting of shareholders shall be the presence of at least two shareholders present in person, by proxy or through a voting deed, who hold at least 25% of our voting rights instead of 33 1/3% of the issued share capital required under Nasdaq requirements. At an adjourned meeting, the presence of any two shareholders present in person, by proxy or through a voting deed shall constitute a quorum.

- *Compensation of officers*. We follow Israeli law and practice with respect to the approval of officer compensation. While our compensation committee currently complies with the provisions of the Nasdaq Listing Rules relating to composition requirements and Israeli law generally requires that the compensation of the chief executive officer and all other executive officers be approved, or recommended to the board for approval, by the compensation committee (and in certain instances, shareholder approval is required), Israeli law includes relief from compensation committee approval in certain instances. For details regarding the approvals required under the Israeli Companies Law and regulation promulgated thereunder for the approval of compensation of the chief executive officer, all other executive officers and directors, see Item 7B "Related Party Transactions — Approval of Related Party Transactions under Israeli Law—Compensation of directors and executive officers." For details regarding the approvals required under the Israeli Companies Law for the approval of compensation of controlling shareholders, see Item 7B "Related Party Transactions — Approval of Related Party Transactions under Israeli Law— Disclosure of personal interests of a controlling shareholder and approval of transactions."

- *Nomination of directors*. Israeli law and our Amended and Restated Articles of Association do not require director nominations to be made by a nominating committee of our board of directors consisting solely of independent directors, as required under the Nasdaq Listing Rules. We rely on the exemption available to foreign private issuers under the Nasdaq Listing Rules and follow Israeli law and practice with regard to the process of nominating directors, in accordance with which directors are recommended by the board of directors for election by shareholders (other than directors elected by our Board of Directors to fill a vacancy). Our Board of Directors has established a non-independent Nominating Committee, whose role is to select and recommend to the Board of Directors for selection, director nominees, while considering the appropriate size and composition of the Board of Directors, the requirements of applicable law regarding service as a member of our Board of Directors and the criteria for the selection of new members of the Board of Directors.

- *Shareholder approval*. We will seek shareholder approval for all corporate actions requiring such approval under the requirements of the Companies Law rather than pursuant to Nasdaq Listing Rule 5635. In particular, under this Nasdaq rule, shareholder approval would otherwise generally be required for: (i) an acquisition of shares or assets of another company that involves the issuance of 20% or more of the acquirer's shares or voting rights or if a director, officer or 5% shareholder has greater than a 5% interest in the target company or the consideration to be received; (ii) the issuance of shares leading to a change of control; (iii) adoption or amendment of equity compensation arrangements; and (iv) issuances of 20% or more of the shares or voting rights (including securities convertible into, or exercisable for, equity) in a private placement if such equity is issued and sold at below the lower of: (x) the Nasdaq Official Closing Price (as reflected on Nasdaq.com) immediately preceding the signing of the applicable binding agreement; and (y) the average Nasdaq Official Closing Price (as reflected on Nasdaq.com) for the five trading days immediately preceding the signing of the applicable binding agreement. Under the Israeli Companies Law, the adoption of, and material changes to, equity-based compensation plans generally require the approval of the board of directors. For details regarding the approvals required under the Israeli Companies Law and regulation promulgated thereunder for the approval of compensation of the chief executive officer, all other executive officers and directors, see Item 7B "Related Party Transactions — Approval of Related Party Transactions under Israeli Law— Compensation of directors and executive officers." For details regarding the approvals required under the Israeli Companies Law for the approval of transactions with and compensation of controlling shareholders, see Item 7B "Related Party Transactions — Approval of Related Party Transactions under Israeli Law— Disclosure of personal interests of a controlling shareholder and approval of transactions." For details regarding the approvals required under the Israeli Companies Law and regulations promulgated thereunder for the approval of significant private placements, see Item 7B "Related Party Transactions — Approval of Related Party Transactions under Israeli Law— Significant Private Placements."

Except as stated above, we currently intend to comply with the rules generally applicable to U.S. domestic companies listed on Nasdaq. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq corporate governance rules. Following our home country governance practices, as opposed to the requirements that would otherwise apply to a company listed on Nasdaq, may provide less protection than is accorded to investors under Nasdaq listing requirements applicable to domestic issuers. For more information, see Item 3.D. "Risk Factors – Risks Related to the Ownership of Our Ordinary Shares - As a "foreign private issuer," we are permitted to follow certain home country corporate governance practices instead of otherwise applicable Nasdaq Capital Market requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers."

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

We have adopted a policy that governs the trading in our securities by our directors, officers, employees and certain other covered persons, and which is reasonably designed to promote compliance with applicable insider trading laws, rules and regulations and applicable Nasdaq listing standards. A copy of our Insider Trading Policy is included as Exhibit 11.1 to this Annual Report.

ITEM 16K. CYBERSECURITY

Cybersecurity Risk Management and Strategy

We have developed and maintain cybersecurity risk management protocols and policies intended to protect the confidentiality, integrity, and availability of our critical systems and information and to manage risks related to our network and cloud security, including security measures and controls to identify, protect and detect cybersecurity risks, and to respond to, and recover from cybersecurity incidents. We provide cybersecurity awareness training for our employees and all new employees must confirm receipt and review of our protocols and policies.

We have engaged a third party to provide operational support for cybersecurity risks and to assess, test or otherwise assist with aspects of our security controls, including our exposure to risks from use of third-party service providers, on an ongoing basis. This forms a critical part of our risk management strategy, which we believe facilitates effective management and mitigation of risks and ensures adherence to applicable regulatory and industry standards.

As of the date of this report, we do not believe that any risks from cybersecurity threats have materially affected, or are reasonably likely to materially affect, us, including our business strategy, results of operations, or financial condition. However, despite our efforts, we cannot eliminate all risks from cybersecurity threats, or provide assurances that we have not experienced an undetected cybersecurity incident. For more information about these risks, please see Item 3.D. "Risk Factors – Risks Related to Our Business, Industry and Regulatory Requirements - Significant disruptions of information technology systems, cyberattacks and other security breaches could compromise our proprietary and confidential information, which could harm our business and reputation."

Cybersecurity Governance

Our audit committee provides oversight of our cybersecurity risk management and of our protocols and processes for managing cybersecurity risks in the context of overall risk management oversight.

Our cybersecurity risk management and the related protocols and processes are overseen by our management team, which will provide applicable updates to our audit committee regarding cybersecurity threats, if and when they materialize, or upon the occurrence of any cybersecurity incident. Our management team is responsible for the supervision of our retained external cybersecurity consultants, who oversee the systems upon which we rely to identify cybersecurity incidents.

PART THREE

ITEM 17. FINANCIAL STATEMENTS

The registrant has responded to Item 18 in lieu of responding to this Item 17.

ITEM 18. FINANCIAL STATEMENTS

The following financial statements, the related notes thereto, and the Report of Independent Public Accountants are filed as a part of this Annual Report on Form 20-F.

Audited Financial Statements

ITEM 19. EXHIBITS

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
1.1	Amended and Restated Articles of Association of the Company (filed as Exhibit 1.1 to Form 20-F filed on April 30, 2024 (File No. 001-36578), and incorporated herein by reference).
2.1	Description of Ordinary Shares (filed as Exhibit 2.1 to Form 20-F filed on April 30, 2024 (File No. 001-36578), and incorporated herein by reference).
4.1	Enlivex Therapeutics Ltd. 2014 Global Share Incentive Plan (filed as Exhibit 4.2 to Form 20-F filed on April 30, 2019 (File No. 001-36578), and incorporated herein by reference).
4.2	Enlivex Therapeutics Ltd. 2019 Global Share Incentive Plan (filed as Exhibit 4.3 to Form 20-F filed April 30, 2020 (File No. 001-36578), and incorporated herein by reference).
4.3	Form of Indemnification Agreement (filed as Exhibit 4.5 to Form 20-F filed on April 30, 2019 (File No. 001-36578), and incorporated herein by reference).
4.4	Agreement between the Company and A.S. Novik, dated as of September 7, 2018 (filed as Exhibit 4.6 to Form 20-F filed on April 30, 2019 (File No. 001-36578), and incorporated herein by reference).
4.5	Employment Agreement between the Company and Oren Hershkovitz, dated as of November 16, 2019 (filed as Exhibit 4.8 to Form 20-F filed April 30, 2020 (File No. 001-36578), and incorporated herein by reference).
4.6	Employment Agreement between the Company and Shachar Shlosberger, dated as of May 3, 2016 (filed as Exhibit 4.8 to Form 20-F filed on April 30, 2019 (File No. 001-36578), and incorporated herein by reference).
4.7	Consulting Agreement between the Company, Hadasit Medical Research Services and Development and Dror Mevorach, dated as of January 1, 2017 (filed as Exhibit 4.9 to Form 20-F filed on April 30, 2019 (File No. 001-36578), and incorporated herein by reference).
4.8	License Agreement between the Company and Tolaren Ltd., dated as of April 30, 2008 (filed as Exhibit 4.10 to Form 20-F filed on April 30, 2019 (File No. 001-36578), and incorporated herein by reference).
4.9	License Agreement between the Company, Hadasit Medical Research Services and Development Ltd. And Yissum Research and Development Company Ltd., dated as of March 12, 2006 (filed as Exhibit 4.11 to Form 20-F filed on April 30, 2019 (File No. 001-36578), and incorporated herein by reference).
4.10	Contingent Value Rights Agreement, dated November 19, 2018 (filed as Exhibit 99.2 to Form 6-K filed on November 19, 2018 (File No. 001-36578), and incorporated herein by reference).
4.11†	Research Agreement, between the Company and Cell Generation (C-G) Ltd., dated May 12, 2019 (filed as Exhibit 4.15 to Form 20-F filed April 30, 2020 (File No. 001-36578), and incorporated herein by reference).
4.12	Form of Underwriter Warrant in the February 2021 offering (filed as Exhibit 10.1 to Form 6-K filed on February 12, 2021 (File No. 001-36578), and incorporated herein by reference).
4.13	Securities Purchase Agreement in the May 2024 offering (filed as Exhibit 1.1 to Form 6-K filed on May 29, 2024 (File No. 001-36578), and incorporated herein by reference).
4.14	Form of Series A Warrant in the May 2024 offering (filed as Exhibit 4.1 to Form 6-K filed on May 29, 2024 (File No. 001-36578), and incorporated herein by reference).
4.15	Form of Series B Warrant in the May 2024 offering (filed as Exhibit 4.2 to Form 6-K filed on May 29, 2024 (File No. 001-36578), and incorporated herein by reference).

4.16	Form of Pre-funded Warrant in the May 2024 offering (filed as Exhibit 4.3 to Form 6-K filed on May 29, 2024 (File No. 001-36578), and incorporated herein by reference).
4.17	Form of Series A Placement Agent Warrant in the May 2024 offering (filed as Exhibit 4.4 to Form 6-K filed on May 29, 2024 (File No. 001-36578),and incorporated herein by reference).
4.18	Form of Series B Placement Agent Warrant in the May 2024 offering (filed as Exhibit 4.5 to Form 6-K filed on May 29, 2024 (File No. 001-36578), and incorporated herein by reference).
4.19	Amendment, dated as of effective as of January 1, 2020, to the Consulting Agreement by and between Enlivex Therapeutics, Ltd. and A.S. Novik Ltd. (filed as Exhibit 4.24 to Form 20-F filed on April 30, 2021 (File No. 001-36578), and incorporated herein by reference).
4.20	Second Amendment to the Consulting Agreement by and between Enlivex Therapeutics, Ltd. and A.S. Novik Ltd, dated November 4, 2021 (filed as Exhibit 4.25 to Form 20-F filed on April 29, 2022 (File No. 001-36578) and incorporated by reference).
4.21*	Third Amendment to the Consulting Agreement, dated November 8, 2024, by and between Enlivex Therapeutics, Ltd. and A.S. Novik Ltd.
4.22	Sales Agreement, dated December 30, 2022, by and among Enlivex Therapeutics Ltd. and Cantor Fitzgerald & Co. and JMP Securities LLC (filed as Exhibit 10.1 to Form 6-K filed on December 30, 2022 (File No. 001-36578), and incorporated herein by reference).
4.23	Agreement, dated as of March 31, 2024, by and between Enlivex Therapeutics R&D Ltd. and BioHarvest Ltd. (filed as Exhibit 4.18 to Form 20-F filed on April 30, 2024 (File No. 001-36578), and incorporated herein by reference).
4.24	Amended and Restated Compensation Policy for Company Office Holders (filed as Exhibit 99.1 to Form 6-K/A filed on October 14, 2024 (File No. 001-36578), and incorporated herein by reference).
8.1*	List of Subsidiaries of Enlivex Therapeutics Ltd.
11.1*	Insider Trading Policy.
12.1*	Certification of the Chief Executive Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934.
12.2*	Certification of the Principal Financial Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934.
13.1+	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, furnished herewith.
13.2+	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, furnished herewith.
15.1*	Consent of Yarel + Partners
97.1	Enlivex Therapeutics Ltd. Executive Officer Clawback Policy (filed as Exhibit 97.1 to Form 20-F filed on April 30, 2024 (File No. 001-36578), and incorporated herein by reference)
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Defeinition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
\+ Furnished herewith.
† Portions of the exhibit have been omitted because such information is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

Enlivex Therapeutics Ltd.

By: /s/ Oren Hershkovitz
Oren Hershkovitz
Chief Executive Officer

Date: April 30, 2025

ENLIVEX THERAPEUTICS LTD.

FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2024

ENLIVEX THERAPEUTICS LTD.

FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of ENLIVEX THERAPEUTICS LTD.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying balance sheets of Enlivex Therapeutics Ltd. and subsidiaries (the "Company") as of December 31, 2024 and 2023, and the related statements of operations, comprehensive loss, shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2024, and the related notes (collectively referred to as the financial statements).

We also have audited the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework (2013) issued by COSO.

Basis for Opinion

The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting.

Our responsibility is to express an opinion on the Company's financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audits of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.

Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements.

Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk.

Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

Critical Audit Matters

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

Accrued clinical trial expenses

Description of the matter -

As discussed in Note 2 to the consolidated financial statements, the Company records costs for clinical trial activities based upon estimates of costs incurred through the balance sheet date that have yet to be invoiced by the contract research organizations and other vendors.

Auditing the Company's accruals for clinical trial activities is challenging due to the fact that information necessary to estimate the accruals for the services that have been received during the reporting period is accumulated from multiple sources, including the Company's personnel who oversee the clinical trial activities, information from service providers and terms and conditions included in the contracts with the service providers.

In addition, in certain circumstances, the determination of the nature and level of services that have been received during the reporting period requires judgment because the historical timing and pattern of vendor invoicing does not correspond to the level of services provided, and there may be delays in invoicing from clinical study sites and other vendors.

How we addressed the matter in our audit –

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls that addressed the identified risks related to the Company's process for recording accrued clinical trial expenses. Our procedures also included, among others, reviewing agreements and contract amendments entered into with vendors in connection with conducting clinical trials, evaluating the significant assumptions described above and the methods used in developing the clinical trial estimates, and calculating the amounts that were unpaid at the balance sheet date. We confirmed selected liabilities recorded directly with the third parties involved in performing research and development services on behalf of the Company. We also made direct inquiries of financial and clinical trial personnel regarding status and progress of clinical trials. We compared the current estimate of expenses incurred to estimates previously made by management and assessed the historical accuracy of management's previous estimates. We also examined invoices issued and payments made to service providers after the consolidated balance sheet date.

/s/ Yarel + Partners
Yarel + Partners
Certified Public Accountants (Isr.)

Tel-Aviv, Israel
March 31, 2025
We have served as the Company's auditor since 2013.

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share data)

	December 31, 2024	December 31, 2023
ASSETS		
Current Assets		
Cash and cash equivalents (note 3)	$ 3,301	$ 813
Short-term interest-bearing deposits (note 4)	20,195	26,507
Prepaid expenses and other receivables (note 5)	2,299	1,336
Assets classified as held for sale (note 16)	198	5,108
Total Current Assets	25,993	33,764
Non-Current Assets		
Property and equipment, net (note 6)	625	1,539
Other assets (notes 7 & 9)	1,069	1,528
Total Non-Current Assets	1,694	3,067
TOTAL ASSETS	$ 27,687	$ 36,831
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities		
Accounts payable trade (note 14)	$ 811	$ 827
Accrued expenses and other liabilities (note 8 & 14)	2,846	4,001
Liability classified as held for sale (note 16)	142	1,233
Total Current Liabilities	3,799	6,061
Non-Current Liabilities		
Other long-term Liabilities (note 9)	299	686
Total Non-Current Liabilities	299	686
Commitments and Contingent Liabilities (note 10)		
TOTAL LIABILITIES	4,098	6,747
SHAREHOLDERS' EQUITY		
Ordinary shares of NIS 0.40 par value: (note 11) Authorized: 45,000,000 shares as of December 31, 2024 and 2023; Issued and outstanding: 23,650,989 and 18,598,555 as of December 31, 2024 and 2023, respectively;	2,685	2,137
Additional paid in capital	146,910	138,939
Accumulated other comprehensive income	1,101	1,101
Accumulated deficit	(127,107)	(112,093)
TOTAL SHAREHOLDERS' EQUITY	23,589	30,084
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 27,687	$ 36,831

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

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

U.S. dollars in thousands (except share and per share data)

	Year ended December 31,		
	2024	**2023**	**2022**
Revenues	$ -	$ -	$ -
Operating expenses:			
Research and development expenses, net (note 17a)	10,623	19,012	18,693
General and administrative expenses (note 17b)	4,913	6,139	7,104
Other expenses (note 17c)	352	4,244	-
	15,888	29,395	25,797
Operating loss	(15,888)	(29,395)	(25,797)
Finance income (expenses), net (note 17d)	874	327	(5,263)
Net loss	$ (15,014)	$ (29,068)	$ (31,060)
Other comprehensive gain			
Total other comprehensive gain	-	-	-
Total comprehensive loss	$ (15,014)	$ (29,068)	$ (31,060)
Basic & diluted loss per share	$ (0.73)	$ (1.56)	$ (1.69)
Weighted average number of shares outstanding	20,513,992	18,574,484	18,394,886

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

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

U.S. dollars in thousands (except share data)

	Ordinary Shares		Additional paid in capital	Accumulated other comprehensive income	Accumulated deficit	Total
	Number of shares	Share capital				
JANUARY 1, 2022	18,331,507	$ 2,107	$ 133,796	$ 1,101	($ 51,965)	$ 85,039
Exercise of options	22,875	3	147	-	-	150
Restricted stock units vested	67,470	7	(7)	-	-	-
Stock based compensation	-	-	2,712	-	-	2,712
Net loss	-	-	-	-	(31,060)	(31,060)
DECEMBER 31, 2022	18,421,852	2,117	136,648	1,101	(83,025)	56,841
Issuance of shares for cash consideration of $513 net of $153 issuance costs	124,171	15	345	-	-	360
Restricted stock units vested	52,532	5	(5)	-	-	-
Stock based compensation	-	-	1,951	-	-	1,951
Net loss	-	-	-	-	(29,068)	(29,068)
DECEMBER 31, 2023	18,598,555	2,137	138,939	1,101	(112,093)	30,084
Issuance of shares for cash consideration of $7,098 net of $646 issuance costs	3,365,014	366	6,086	-	-	6,452
Restricted stock units vested	175,991	19	(19)	-	-	-
Exercise of Warrants	1,511,429	163	(161)	-	-	2
Stock based compensation	-	-	2,065	-	-	2,065
Net loss	-	-	-	-	(15,014)	(15,014)
DECEMBER 31, 2024	23,650,989	$ 2,685	$ 146,910	$ 1,101	$ (127,107)	$ 23,589

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,		
	2024	**2023**	**2022**
Cash flows from operating activities			
Net loss	$ (15,014)	$ (29,068)	$ (31,060)
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation	545	835	777
Capital gain on sale of property and equipment	(82)	(20)	
Loss (income) on marketable securities and short-term bank deposits	(558)	(343)	1,983
Loss on assets and liabilities classified as held for sale	957	4,244	-
Non-cash operating lease expenses	297	696	831
Share-based compensation	2,065	1,951	2,712
Changes in operating assets and liability items:			
Increase in prepaid expenses and other receivables	433	608	278
(Decrease) increase in accounts payable trade	(16)	(1,121)	1,168
(Decrease) increase in accrued expenses and other liabilities	(1,044)	(350)	684
Decrease in liability classified as held for sale	(327)	(101)	-
Operating lease liabilities	(264)	(854)	(1,326)
Net cash used in operating activities	(13,008)	(23,523)	(23,953)
Cash flows from investing activities			
Purchase of property and equipment	(103)	(236)	(8,122)
Proceeds from sale of property and equipment	184	133	-
Proceeds from sale of assets and liabilities classified as held for sale	2,109	-	-
Investment in short-term interest-bearing bank deposits	(32,370)	(26,166)	(299)
Release of short-term interest-bearing bank deposits	39,239	301	10,004
Purchases of marketable securities	-	-	(1,608)
Proceeds from sale of marketable securities	-	-	62,549
Net cash provided by (used in) investing activities	9,059	(25,968)	62,524
Cash flows from financing activities			
Proceeds from issuance of shares and warrants, net	6,452	360	-
Proceeds from exercise of warrants	2	-	-
Proceeds from exercise of options	-	-	150
Net cash provided by financing activities	6,454	360	150
Increase (decrease) in cash, cash equivalents and restricted cash	2,505	(49,131)	38,721
Cash, cash equivalents and restricted cash - beginning of year	1,226	50,357	11,636
Cash, cash equivalents and restricted cash - end of year	$ 3,731	$ 1,226	$ 50,357
Supplemental disclosures of cash flow information:			
Cash paid for taxes	$ -	$ -	$ -
Cash received for interest, net	$ 1,475	$ 1,565	$ 835

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – GENERAL INFORMATION

a. General

Enlivex Therapeutics Ltd. (the "Parent" and, including its consolidated subsidiaries, "we", "us", "our" or the "Company") is a clinical-stage macrophage reprogramming immunotherapy company originally incorporated on January 22, 2012 under the laws of the State of Israel.

The Company is developing Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state. Resetting non-homeostatic macrophages into their homeostatic state is critical for immune system rebalancing and resolution of debilitating and life-threatening conditions. Non-homeostatic macrophages contribute significantly to the severity of certain diseases, which include osteoarthritis, sepsis and others.

Allocetra™ is based on the discoveries of Professor Dror Mevorach, an expert on immune activity, macrophage activation and clearance of dying (apoptotic) cells, in his laboratory in the Hadassah University Hospital located in the State of Israel.

The Company's ordinary shares, par value of NIS 0.40 per share ("Ordinary Shares"), are traded under the symbol "ENLV" on both the Nasdaq Capital Market and on the Tel Aviv Stock Exchange.

b. Financial resources

The Company devotes substantially all of its efforts toward research and development activities and raising capital to support such activities. The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding before the Company achieves sustainable revenues and profit from operations.

Research and development activities have required significant capital investment since the Company's inception. The Company expects that its operations will require additional cash investment to pursue the Company's research and development activities, including preclinical studies, formulation development, clinical trials and related drug manufacturing. The Company has not generated any revenues or product sales and has not achieved profitable operations or positive cash flow from operations. The Company has incurred net losses since its inception, and, as of December 31, 2024, had an accumulated deficit of $127,107 thousand.

The Company expects to continue to incur losses for at least the next several years, and the Company will need to raise debt or equity financing or enter into partnerships to fund its development. If the Company is not able to achieve its funding requirements, it may be required to reduce discretionary spending, may not be able to continue the development of its product candidates and may be required to delay its development programs, which could have a material adverse effect on the Company's ability to achieve its intended business objectives. There can be no assurances that additional financing will be secured or, if secured, will be on favorable terms.

The ability of the Company to transition to profitability in the longer term is dependent on a combination of factors, including (i) successfully obtaining additional financing discussed above; (ii) the Company's ability to successfully begin marketing of its product candidates or complete revenue-generating partnerships with other companies; (iii) the success of its research and development; (iv) the impact of competition from other biotechnology and pharmaceutical companies that may develop competitive therapies; and (v) regulatory approval and market acceptance of the Company's product candidates.

The Company's management and board of directors (the "Board") are of the opinion that the Company's current financial resources will be sufficient to continue the development of the Company's product candidates for at least twelve months following the filing of these financial statements with the U.S. Securities and Exchange Commission. The Company may determine, however, to raise additional capital during such period as the Board deems prudent. The Company's management plans to finance its operations with issuances of the Company's equity securities and, in the longer term, revenues. There are no assurances, however, that the Company will be successful in obtaining the financing necessary for its long-term development. The Company's ability to continue to operate in the long term is dependent upon additional financial support.

c. Approval of financial statements

These financial statements were approved by the Board on March 31, 2025.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The Company's audited consolidated financial statements as of December 31, 2024 and 2023 and for each of the years in the three-year period ended December 31, 2024 have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"). Any reference in these notes to applicable guidance refers to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements include the accounts of the Company, Enlivex Therapeutics R&D Ltd. and Enlivex Therapeutics RDO Ltd., its wholly owned subsidiaries incorporated in Israel, and Enlivex Therapeutics Inc., its wholly owned subsidiary incorporated in the State of Delaware.

All intercompany accounts and transactions have been eliminated in consolidation.

The significant accounting policies described below have been applied on a consistent basis for all years presented.
The financial statements have been prepared on the basis of historical cost, subject to adjustment of financial assets and liabilities to their fair value through profit or loss. The Company classifies its expenses on the statement of comprehensive loss based on the operating characteristics of such expenses.

Use of estimates

The preparation of the financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions, it also requires that management exercise its judgment in applying the Company's accounting policies. The Company's management believes that the estimates, judgments and assumptions used were reasonable based upon information available at the time they were made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts in the statements of operations during each reporting period. Actual results could differ materially from those estimates.

Functional currency and translation to the reporting currency

The functional currency of the Company is the U.S. dollar because the U.S. dollar is the currency of the primary economic environment in which the Company operates and expects to continue to operate in the foreseeable future.

Transactions other than in the functional currency are translated at the approximate U.S. dollar exchange rate in effect at the time of the transaction.

The following table presents data regarding U.S. dollar exchange rates with respect to the New Israeli Shekel ("NIS"):

	At December 31,		
	2024	**2023**	**2022**
1 U.S. $ =	NIS 3.647	NIS 3.627	NIS 3.519
Increase during the year	0.55%	3.07%	13.15%

Cash and cash equivalents

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with original maturities of three months or less at acquisition.

Restricted cash

Amounts included in restricted cash are held in interest bearing saving accounts and represent cash amounts required to be set aside by a contractual agreement for the rental of the Company's premises and for credit cards and cash amounts required to be set aside by other contractual agreements.

Marketable securities

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The Company may invest its excess cash in mutual funds that are classified based on the nature of their underlying securities and their availability for use in current operations. The Company's marketable equity securities are measured at fair value with gains and losses recognized in finance income (expenses), net.

Net losses recognized on equity securities for the years ended December 31, 2024, 2023 and 2022 were $0, $0 and $(1,983) thousand, respectively.

Property and equipment

Property and equipment are stated at historical cost less depreciation. Assets are depreciated using the straight-line method over the estimated useful lives of the assets. The annual depreciation rates are as follows:

	%
Computers	33.33
Office furniture and equipment	7
Leasehold improvements	16.67
Laboratory equipment	15-30

Impairment of non-financial assets

The long-lived assets of the Company are reviewed for impairment in accordance with ASC 360, "Property, Plant, and Equipment", whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. ASC 360 requires three steps to identify, recognize and measure the impairment of a long-lived asset (asset group) to be held and used:

Step 1 - consider whether indicators of impairment are present;

Step 2 - if indicators of impairment are present, perform a recoverability test comparing the sum of the estimated undiscounted cash flows attributable to the long-lived asset or asset group in question to the carrying amount of the long-lived asset or asset group; and

Step 3 - if the undiscounted cash flows used in the recoverability test are less than the carrying amount of the long-lived asset (asset group), estimate the fair value of the long-lived asset or asset group and recognize an impairment loss when the carrying amount of the long-lived asset or asset group exceeds the estimated fair value.

During the years 2024, 2023, and 2022, no impairment losses were identified, other than with respect to assets held for sale. See Note 16.

Segment reporting

An operating segment is identified as a component of an enterprise that engages in business activities about which separate discrete financial information and operating results are regularly reviewed by the chief operating decision-maker ("CODM") in making decisions regarding resource allocation and assessing performance.

The Company's CODM is the Company's senior executive management, which is composed of the Executive Chairman of the Board, the Chief Executive Officer and the Vice President Medical Officer.

The Company operates in a single operating segment – the development of a universal, off-the-shelf cell therapy platform designed to restore the homeostatic state of macrophages for the treatment of inflammatory diseases.

The CODM assesses performance for the segment and decides how to allocate resources based on consolidated net loss as reported on the statement of operations, after taking into account the Company's strategic priorities, its cash balance, and its expected use of cash.

The CODM uses consolidated net loss to monitor budget versus actual results on a monthly basis to timely identify deviations from expected results, which is used in assessing performance and deciding where to allocate resources predominantly in the annual budget and forecasting process.

As of December 31, 2024, and 2023, all of the Company's long-lived assets were located in Israel.

All required significant financial segment information can be found within the consolidated financial statements.

Leases

In accordance with ASU No. 2016-02, Leases (Topic 842), right-of-use ("ROU") assets represent our right to use the underlying leased assets over the lease term, and lease liabilities represent our obligation to make lease payments arising from the related leases. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. Lease terms may include options to extend or terminate the lease when we believe it is reasonably certain that we will exercise such options. Operating lease ROU assets are reported in other assets, and operating lease liabilities are reported in accounts payable and accrued liabilities (current), and other long-term liabilities (non-current) in our consolidated balance sheets.

Because the Company's leases do not provide an implicit interest rate, the Company uses its estimated incremental borrowing rate to determine the present value of lease payments. Lease expenses for operating lease payments are recognized on a straight-line basis over the lease term, and the related ROU assets and liabilities are reduced to the present value of the remaining lease payments at the end of each period. Short-term leases (with a term of 12 months or less) are not recorded as ROU assets or liabilities in the consolidated balance sheets. The Company's lease agreements include rental payments that adjust periodically for inflation and do not contain any material residual value guarantees or material restrictive covenants.

Assets and liabilities classified as held for sale

The Company classifies an asset group (an "asset") as held for sale in the period during which (i) the Company has approved and committed to a plan to sell the asset, (ii) the asset is available for immediate sale in its present condition, (iii) an active program to locate a buyer and other actions required to sell the asset have been initiated, (iv) the sale of the asset is probable and transfer of the asset is expected to qualify for recognition as a completed sale within one year, (v) the asset is being actively marketed for sale at a price that is reasonable in relation to its current fair value, and (vi) it is unlikely that significant changes to the plan will be made or that the plan will be abandoned. The Company initially and subsequently measures a long-lived asset that is classified as held for sale at the lower of its carrying value or fair value less any costs to sell. Any loss resulting from this measurement is recognized in operating loss for the period in which the held for sale criteria are met. Upon designation as an asset held for sale, the Company stops recording depreciation or amortization expense on the asset. The Company assesses the fair value of assets held for sale less any costs to sell at each reporting period until the asset is no longer classified as held for sale.

Assets and liabilities classified as held for sale are presented separately as current items in the consolidated balance sheets. The Company classified certain long-lived assets and liabilities as held for sale as of December 31, 2024 and 2023 and recorded impairment charges of $957 thousand and $4,244 thousand, respectively, for the years then ended.

Stock-based compensation

The Company accounts for stock-based compensation arrangements with employees and non-employees using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments including stock options. The fair value method requires the Company to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. The Company uses the Black-Scholes option-pricing model to estimate the fair value of options granted that are expensed on a straight-line basis over the requisite service period, which is generally the vesting period. The Company accounts for forfeitures as they occur. Option valuation models, including the Black-Scholes option-pricing model, require the input of several assumptions. Changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free interest rate, expected dividend yield, expected volatility and the expected life of the award.

Employee benefits

The Company is required by Israeli law to make severance payments to Israeli employees upon their dismissal or termination of employment in certain circumstances. The Company operates a number of post-employment defined contribution plans. A defined contribution plan is a program that benefits an employee after termination of employment, under which the Company regularly makes fixed payments to a fund administered by a separate and independent entity so that the Company has no legal or constructive obligation to pay additional contributions if such fund does not contain sufficient assets to pay all employees the benefits to which they may be entitled relating to employee service in the current and prior periods. The fund assets are not included in the Company's consolidated balance sheets. The Company operates pension and severance compensation plans subject to Section 14 of the Israeli Severance Pay Law. The plans are funded through payments to insurance companies or pension funds administered by trustees. In accordance with its terms, the plans meet the definition of a defined contribution plan.

Short term employee benefits - Labor laws in Israel entitle every employee to vacation days, paid sick leave and recreation pay, computed annually. The Company recognizes a liability and an expense in respect of vacation and recreation pay based on the individual entitlement of each employee.

Revenue recognition

The Company has not yet generated any revenue from product sales or otherwise.

Research and development expenses, net

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, subcontractors and materials used for research and development activities, including clinical trials, manufacturing costs, consulting fees and facilities and overhead costs. All costs associated with research and developments are expensed as incurred. As of December 31, 2024, the Company had not yet capitalized development expenses. Costs incurred in purchasing technology assets and intellectual property are charged to research and development expense if the technology has not been conclusively proven to be feasible and has no alternative future use.

Grants received from Israel Innovation Authority, Ministry of Industry, Trade and Labor (the "IIA"), are recognized when the grant becomes receivable, provided there is reasonable assurance that the Company will comply with the conditions attached to the grant and there was reasonable assurance the grant will be received. The grant is deducted from the research and development expenses as the applicable costs are incurred.

Clinical trial expenses are charged to research and development expenses as incurred. The Company's objective is to reflect the appropriate trial expense in the consolidated financial statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made, the payments are recorded as assets, which are expensed as services are rendered.

Clinical trial accruals

The Company makes estimates of its accrued expenses as of each balance sheet date in the financial statements based on the facts and circumstances known at that time. Accrued expenses for preclinical studies and clinical trials are based on estimates of costs incurred and fees that may be associated with services provided by contract research organizations, clinical trial sites and other clinical trial-related activities. Payments under certain contracts with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of clinical trial milestones. If possible, the Company obtains information regarding unbilled services directly from these service providers. However, the Company may be required to estimate these services based on other available information. If the Company underestimates or overestimates the activities or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, estimated accrued liabilities have approximated actual expense incurred.

General and administrative

General and administrative expenses consist of compensation and related benefits, including stock-based compensation, for executive and corporate personnel; professional and consulting fees; and allocated overhead, such as facilities and equipment rent and maintenance, insurance costs allocated to general and administrative expenses, costs of patent applications, maintenance, depreciation expense and other miscellaneous expenses which are allocated to general and administrative expense.

Patents

The Company expenses all costs associated with patents (including application fees, and the legal and consulting expenses related to making such applications) for product candidates under development as incurred. As a result of the Company's research and development efforts, the Company regularly applies for patents to protect proprietary technology and inventions. To date, the Company has not capitalized patent costs. The Company recorded charges to general and administrative expenses in the accompanying statements of operations and comprehensive loss of approximately $180 thousand, $391 thousand and $536 thousand for the years ended December 31, 2024, 2023 and 2022, respectively, related to patent costs.

Income taxes

The Company accounts for income taxes in accordance with ASC 740-10 "Accounting for Income Taxes", which requires the use of the liability method of accounting for income taxes, whereby deferred tax asset and liability account balances are determined based on the differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

As the Company is currently engaged primarily in development activities and is not expected to generate taxable income in the foreseeable future, the Company provides a valuation allowance to reduce deferred tax assets to their estimated realizable value.

ASC 740 contains a two-step approach to recognizing and measuring a liability for uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. As of December 31, 2024, the Company had no accruals for uncertain tax positions.

Loss per share

Basic loss per share is calculated based on the weighted average number of Ordinary Shares outstanding during each year. Diluted net loss per share is calculated based on the weighted average number of Ordinary Shares outstanding during each year, plus dilutive potential shares in accordance with ASC 260, "Earnings per Share."

All outstanding restricted stock units, options and warrants for the years ended December 31, 2024, 2023 and 2022 have been excluded from the calculation of diluted net loss per share because all such securities are anti-dilutive for all such years. For the years ended December 31, 2024, 2023 and 2022, the total weighted average number of shares related to outstanding potential shares excluded from the calculations of diluted net loss per share was 3,683,488, 3,144,994 and 2,902,423, respectively. The following data show the amounts used in computing loss per share and the effect on loss:

(in thousands except share and per share data)	Year ended December 31,		
Basic and diluted loss per share:	**2024**	**2023**	**2022**
Loss from continuing operations	$ (15,014)	$ (29,068)	$ (31,060)
Number of common shares at the beginning of the year	18,598,555	18,421,852	18,331,507
Weighted average number of shares issued for cash	1,528,695	110,249	-
Weighted average number of stock options exercised	-	-	13,015
Weighted average number of restricted stock units vested	72,826	42,383	50,364
Weighted average number of warrants exercised	313,916	-	-
Number of shares used in per share computation	20,513,992	18,574,484	18,394,886
Basic and diluted net loss per share	$ (0.73)	$ (1.56)	$ (1.69)

Concentrations of credit risk:

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents, restricted cash and bank deposits.

Cash and cash equivalents, restricted cash and deposits are invested in major banks in Israel. Such deposits in Israel are not insured. Management believes that the financial institutions that hold the Company's investments are financially sound and, accordingly, minimal credit risk exists with respect to these investments.

The Company had no foreign exchange contracts or any other hedging arrangements as of December 31, 2024.

Fair value of financial instruments

The Company applies ASC 820, "Fair Value Measurements and Disclosures" ("ASC 820"),the guidance defines fair value, provides guidance for measuring fair value and requires certain disclosures. The guidance does not apply to measurements related to share-based payments. The guidance discusses valuation techniques such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The guidance establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels.

The Company's financial instruments consist of cash and cash equivalents, restricted cash, deposits, accounts receivable, accounts payable, accrued liabilities, and lease liability. Fair value estimates of these instruments are made at each reporting period end based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, restricted cash, accounts receivable, accounts payable, and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. The Company believes that the fair value of the lease liability approximates its carrying value.

ASC 820 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company.

The financial instruments presented on the balance sheet at fair value are grouped into classes with similar characteristics using the following fair value hierarchy which is determined based on the source of input used in measuring fair value:

Level 1 - quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 - inputs other than quoted prices included within level 1 that are observable either directly or indirectly.

Level 3 - inputs that are not based on observable market data (valuation techniques which use inputs that are not based on observable market data).

Accumulated other comprehensive income (loss)

Comprehensive income (loss) is the change in shareholders' equity from transactions and other events and circumstances other than those resulting from investments by shareholders and distributions to shareholders.

The Company accounts for comprehensive income (loss) in accordance with ASC 220, "Comprehensive Income". This statement establishes standards for the reporting and display of comprehensive income (loss) and its components in a full set of general-purpose financial statements.

Reclassification

Certain comparative figures have been reclassified to conform to the current year presentation. Such reclassifications did not have any significant impact on the Company's equity, net income or cash flows.

Recently Adopted Accounting Standards

From time to time, the Financial Accounting Standards Board (the "FASB") or other standard-setting bodies issue accounting standards that are adopted by the Company as of the specified effective date.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU No. 2023-07"), which intends to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The amendments in this ASU are effective for public business entities for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company adopted ASU No. 2023-07 on January 1, 2024 retrospectively, and the adoption did not have a material effect on the Company's consolidated financial statements. Refer to "Segment reporting" in Note 2 for further details.

In November 2024, the FASB issued ASU No. 2024-04, Debt-Debt with Conversion and Other Options (Subtopic 470-20) ("ASU No. 2024-04"), which intends to clarify the conditions in which induced conversion applies to convertible debt by outlining three criteria that must be met for an entity to apply the induced conversion model. The amendments in this ASU are effective for annual reporting periods beginning after December 15, 2025 (and interim reporting periods within those annual reporting periods). Early adoption is permitted as of the beginning of a reporting period if the entity has also adopted ASU 2020-06 for that period. The Company early adopted ASU 2024-04 on January 1, 2024 on a prospective basis, and the adoption did not have a material effect on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Effective

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which is intended to provide enhancements to annual income tax disclosures. The standard will require more detailed information in the rate reconciliation table and for income taxes paid, among other enhancements. The standard is effective for years beginning after December 15, 2024, and early adoption is permitted. The Company does not believe that adoption of this ASU will have a material impact on the Company's consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40) ("ASU No. 2024-03"), which requires disaggregated disclosure of income statement expenses for public business entities. The ASU does not change the expense captions an entity presents on the face of the income statement; rather, it requires disaggregation of certain expense captions into specified categories in disclosures within the footnotes to the financial statements. For public business entities, it is effective for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted.

The amendments in this ASU will apply prospectively; however, public business entities are permitted to apply the amendments in the ASU retrospectively, The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

NOTE 3 – CASH, CASH EQUIVALENTS AND RESTRICTED CASH

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheet, including location of amounts reported in the accompanying consolidated balance sheets, that sum to the total of the same such amounts shown in the statement of cash flows.

(in thousands)	December 31, 2024	December 31, 2023
Cash held in banks	$ 2,257	$ 813
Bank deposits in U.S. $ with original maturities of three months or less (annual average interest rate 2024 - 3.16%)	1,044	-
Total cash and cash equivalents	3,301	813
Restricted cash – current – Prepaid expenses and other receivables	113	113
Restricted cash – noncurrent – Other assets	317	300
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 3,731	$ 1,226

NOTE 4 – SHORT TERM DEPOSITS

(in thousands)	December 31, 2024	December 31, 2023
Bank deposits in U.S. $ (annual average interest rates 5.863% and 6.195%)	$ 9,259	$ 6,240
Bank deposits in NIS (annual average interest rates 4.410% and 4.568%)	10,936	20,267
	$ 20,195	$ 26,507

NOTE 5 – PREPAID EXPENSES AND OTHER RECEIVABLES

(in thousands)	December 31, 2024	December 31, 2023
Prepaid expenses	$ 884	$ 1,107
Tax authorities	68	116
Receivables on account of assets sold	1,234	-
Others	113	113
	$ 2,299	$ 1,336

NOTE 6 – PROPERTY AND EQUIPMENT

Property and equipment, net consists of the following:

(in thousands)	December 31, 2024	December 31, 2023
Cost:		
Laboratory equipment	$ 2,094	$ 2,387
Computers	462	342
Office furniture & equipment	124	249
Leasehold improvements	947	1,431
Total cost	3,627	4,409
Accumulated depreciation:		
Laboratory equipment	1,969	1,887
Computers	328	264
Office furniture & equipment	40	41
Leasehold improvements	665	678
Total accumulated depreciation	3,002	2,870
Depreciated cost	$ 625	$ 1,539

For the years ended December 31, 2024, 2023 and 2022, depreciation expenses were $545 thousand, $835 thousand and $777 thousand, respectively.

NOTE 7 – OTHER ASSETS

(in thousands)	December 31, 2024	December 31, 2023
Restricted cash	$ 317	$ 300
Receivables on account of assets sold	206	-
Long term deposit	8	8
Long-term prepaid expenses	10	179
Right-of-Use assets, net	528	1,041
	$ 1,069	$ 1,528

NOTE 8 – ACCRUED EXPENSES AND OTHER LIABILITIES

(in thousands)	December 31, 2024	December 31, 2023
Vacation, convalescence and bonus accruals	$ 1,407	$ 889
Employees and payroll related	279	422
Short-term operating lease liabilities	235	346
Accrued expenses and other	925	2,344
	$ 2,846	$ 4,001

NOTE 9 – LEASES

The Company determines if a contract contains a lease at inception and recognizes operating lease ROU assets and operating lease liabilities based on the present value of the future minimum lease payments at the commencement date. As the Company's leases do not provide an implicit interest rate, management develops incremental borrowing rates based on the information available at the commencement date in determining the present value of future payments. Lease expenses are recognized on a straight-line basis over the lease term.

At December 31, 2024, the Company's operating leases were as follows:

In July 2018, the Company entered into a lease agreement for offices, laboratory space and parking at the Science Park in Nes Ziona, Israel for approximately 420 square meters of space. The lease for this space expired on August 31, 2023, at which time the Company extended the lease for an additional 60-month period.

In October 2020, the Company entered into an additional lease agreement at the Science Park in Nes Ziona, Israel for approximately 421 square meters of space. The lease for this space expires on September 30, 2025, at which time the Company may extend the lease for an additional 33-month period.

On July 29, 2021, the Company entered into an additional lease agreement in Nes Ziona, which added 455 square meters of office space to the existing leased space. The lease for the additional 455 square meters is for a period of 63 months, which commenced on August 1, 2021. The lease expires on October 31, 2026 with an option to extend the lease for an additional 22 months.

At the time the Company entered into each of the Nes Ziona lease agreements, the Company was not reasonably certain that it would exercise the extension option contained therein and therefore did not include the extension options in the determination of the total lease terms for accounting purposes.

During 2024, the Company decided to sell the lease rights under the lease agreement entered into on July 29, 2021, together with the leasehold improvements installed in the leased property. The ROU asset and lease liability were recorded as Assets classified as held for sale and Liability classified as held for sale, respectively. See note 16.

As of December 31, 2024 the Company was a party to seven vehicle lease agreements. All vehicle lease agreements are for 36 months periods.

(in thousands)	Year ended December 31, 2024	2023	2022
The components of lease expense were as follows: Operating leases expenses	$ 324	$ 863	$ 1,037
Cash flow information related to operating leases: Cash used in operating activities	$ 312	$ 766	$ 875
Non-cash activity - Right of use assets obtained in exchange for new operating lease liabilities	$ 25	$ 689	$ 179

Supplemental information related to operating leases, including location of amounts reported in the accompanying consolidated balance sheets, follows:

(in thousands)	December 31, 2024	2023
Other assets - ROU assets	$ 1,176	$ 2,161
Accumulated amortization	648	1,120
Operating lease ROU assets, net	$ 528	$ 1,041
Lease liabilities – current - Accounts payable and accrued liabilities	$ 235	$ 346
Lease liabilities – noncurrent	299	686
Total operating lease liabilities	$ 534	$ 1,032
Weighted average remaining lease term in years	2.85	3.3
Weighted average annual discount rate	8.5%	6.7%

(in thousands)

Maturities of undiscounted operating lease liabilities as of December 31, 2024, were as follows:

2025	$ 275
2026	125
2027	121
2028	88
Total undiscounted lease liability	609
Less: Imputed interest	(75)
Present value of lease liabilities	$ 534

NOTE 10 – COMMITMENTS AND CONTINGENT LIABILITIES

a) Obligation to pay royalties to the State of Israel

The Company is required to pay royalties to the State of Israel (represented by the IIA), computed on the basis of proceeds from the sale or license of products for development supported by IIA grants. These royalties are generally 3% - 5% of sales until repayment of 100% of the grants (linked to the U.S. dollar) received by the Company plus annual interest.

The aggregate contingent obligation payable by the Company to the State of Israel as of December 31, 2024 was approximately $9.8 million, which represented the gross amount of grants received by the Company from the IIA, including accrued interest. As of December 31, 2024, the Company had not paid any royalties to the IIA.

In January 2022, the Company submitted a new grant application to the IIA to approve an expenditure of $4.8 million for its clinical development program for the prevention of cytokine storms and organ dysfunction associated with sepsis for a period that commenced January 1, 2022 and ended December 31, 2022. In May 2022, the IIA approved this application in the amount of $1 million for expenses associated with the ongoing sepsis clinical Phase II trial.

b) Executive Chairman Agreement

On September 7, 2018 the Company entered into an agreement with its Executive Chairman. Pursuant to the agreement, upon termination of the Chairman's board service, under certain conditions defined in the agreement, the Executive Chairman will be entitled to receive an amount of up to three times his then annual base retainer plus the value of accrued benefits. As of December 31, 2024, no termination liability was accrued or payable.

On November 4, 2021 the Company and the Executive Chairman entered into an amendment to the foregoing agreement, granting the Executive Chairman 3.33% of future gross proceeds actually received by the Company during the first five (5) years following consummation of a commercial transaction involving the Company or sale of the Company, in each case as defined in the amendment. In the case of a commercial transaction, the fee with respect to such commercial transaction would become payable only once the aggregate consideration actually received by the Company in respect of such commercial transaction is equal to or greater than $20 million.

c) Litigation

From time to time, the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. Management believes that there were no claims or actions pending against the Company at December 31, 2024 which will have, individually or in the aggregate, a material adverse effect on the Company's business, liquidity, financial position or results of operations. Litigation, however, is subject to inherent uncertainties, and an adverse result in such matters may arise from time to time that may harm the Company's business.

NOTE 11 – EQUITY

a) Ordinary Shares confer upon their holders the right to attend and vote in general shareholders' meetings, to share in the distribution of dividends if and when declared by the Board and the right to receive assets of the Company upon its liquidation.

b) On May 27, 2024, the Company entered into a securities purchase agreement with a single institutional investor in connection with the issuance and sale by the Company in a registered direct offering (the "Offering") of (i) 2,060,000 Ordinary Shares, (ii) pre-funded warrants to purchase up to 1,511,429 Ordinary Shares (the "Pre-Funded Warrants"), (iii) Series A warrants to purchase up to 3,571,429 Ordinary Shares (the "Series A Warrants") and (iv) Series B warrants to purchase up to 3,571,429 Ordinary Shares (the "Series B Warrants" and, together with the Series A Warrants, the "Investor Warrants"), at a combined purchase price of (a) $1.40 per Ordinary Share and the associated Investor Warrants, each to purchase one Ordinary Share, and (b) $1.399 per Pre-Funded Warrant and the associated Investor Warrants, each to purchase one Ordinary Share, pursuant to the Company's effective shelf registration statement on Form F-3 (File No. 333-364561) and related base prospectus and prospectus supplement.

Each Investor Warrant has an exercise price of $1.40 per Ordinary Share and became immediately exercisable upon issuance.

The Series A Warrants expire upon the earlier of 18 months following the issuance date and 60 days following the Company's public announcement of positive topline trial results of Allocetra™ for the treatment of moderate-to-severe knee osteoarthritis (the "Series A Milestone Event").

The Series B warrants expire upon the earlier of five and one-half years following the issuance date and 60 days following the Company's public announcement of its filing with the U.S. Food and Drug Administration for approval for Allocetra™'s osteoarthritis related indication (the "Series B Milestone Event").

Each Pre-Funded Warrant had an exercise price of $0.001 per Ordinary Share and became immediately exercisable upon issuance with no expiration date.

H.C. Wainwright & Co. ("Wainwright") acted as placement agent in connection with the Offering, and in consideration therefor the Company agreed to register and issue to Wainwright warrants (the "Placement Agent Warrants") to purchase up to 250,000 Ordinary Shares. The Placement Agent Warrants comprise Series A Warrants to purchase 125,000 Ordinary Shares and Series B Warrants to purchase 125,000 Ordinary Shares, containing the same terms as the Investor Warrants, except that they are exercisable at a price of $1.75 per Ordinary Share, and the Series B Warrants will expire upon the earlier of five years following the commencement of the sale of the securities offered in the Offering and 60 days following the Series B Milestone Event.

In addition, the Company agreed to pay Wainwright an aggregate cash fee equal to 7% of the gross proceeds raised in the Offering, a management fee equal to 1% of the gross proceeds raised in the Offering and $90,950 for various fees and expenses.

The Offering closed on May 29, 2024. The net proceeds from the Offering were approximately $4.5 million after deducting Wainwright's fees and other expenses relating to the Offering.

During the second half of 2024, all Pre-Funded Warrants were exercised for 1,511,429 Ordinary Shares.

c) During 2024, the Company entered into an investor relations agreement with a third party for monthly cash compensation of $8 thousand and the issuance of 50,000 warrants to purchase Ordinary Shares, of which 25,000 have an exercise price of $3.25 per share and 25,000 have an exercise price of $4.25 per share. The warrants were issued on November 26, 2024, become exercisable on November 26, 2024 and will expire on February 2, 2027.

d) On December 30, 2022 the Company entered into an agreement (the "ATM Agreement"), with Cantor Fitzgerald & Co. and JMP Securities LLC (each referred to as an "Agent", and together, the "Agents"), as sales agents, pursuant to which the Company may elect to sell, but is not obligated to sell, Ordinary Shares having an aggregate offering price of up to $100,000,000 from time to time through the Agents. The offer and sale of Ordinary Shares by the Company under the ATM Agreement may be made in transactions that will be deemed to be "at-the-market" offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made directly on or through the Nasdaq Capital Market, or any other existing trading market in the United States for the Ordinary Shares, sales made to or through a market maker other than on an exchange or otherwise, directly to an Agent as principal, in negotiated transactions, or in any other method permitted by law, which may include block trades. The Company has agreed to pay the Agents an aggregate commission of 3% of the gross sales price from each sale of Ordinary Shares under the ATM Agreement.

During 2024 and 2023, the Company sold an aggregate of 1,305,014 and 124,171 Ordinary Shares, respectively, under the ATM Agreement, resulting in a gross aggregate offering price of $2,100 thousand and $513 thousand at a gross average price per share of $1.61 and $4.11, respectively. Issuance expenses totaled $63 thousand and $153 thousand, respectively.

e) Each of the Company's outstanding warrants entitles the holder to exercise such warrant for one Ordinary Share and does not confer upon such holder any rights as an ordinary shareholder until such holder exercises such holder's warrants and acquires the Ordinary Shares.

All Company warrants are classified as a component of shareholders' equity because such warrants are free standing financial instruments that are legally detachable, separately exercisable, do not embody an obligation for the Company to repurchase its own shares, and permit the holders to receive a fixed number of Ordinary Shares upon exercise, requires physical settlement and do not provide any guarantee of value or return (unless, in accordance with ASC 815-40-55-3, there is a fundamental transaction, as defined in the warrant agreements, which allows the holders of the warrants to receive the same form of consideration payable to the holders of Ordinary Shares, in which case equity treatment is not precluded).

The following table contains additional information concerning warrants activity for the years 2024 and 2023:

	For the year ended December 31,			
	2024		2023	
	Number of warrants	Weighted average exercise price	Number of warrants	Weighted average exercise price
Outstanding at the beginning of the year	202,251	$ 23.31	202,251	$ 23.31
Issued	8,954,287	$ 1.19	-	-
Exercised	(1,511,429)	$ 0.001	-	$ -
Outstanding and exercisable at year-end	7,645,109	$ 2.007	202,251	$ 23.31

Set forth below is data regarding the range of exercise prices and remaining contractual life (in years) for warrants outstanding at December 31, 2024:

Number of Warrants	Exercise Price Per Share	Issuance date	Expiration date
22,750	$ 10.00	February 26, 2020	February 24, 2025
160,727	$ 25.00	February 12, 2021	February 9, 2026
18,774	$ 25.00	February 17, 2021	February 9, 2026
3,571,429	$ 1.40	May 29, 2024	December 1, 2025(i)
3,571,429	$ 1.40	May 29, 2024	November 29, 2029 (ii)
125,000	$ 1.75	May 29, 2024	December 1, 2025(i)
125,000	$ 1.75	May 29, 2024	May 27, 2029 (iii)
25,000	$ 3.25	November 26, 2024	February 2, 2027
25,000	$ 4.25	November 26, 2024	February 2, 2027
7,645,109			

(i) The earlier of (a) December 1, 2025 and (b) the 60th day following the occurrence of the Series A Milestone Event.
(ii) The earlier of (a) November 29, 2029 and (b) the 60th day following the occurrence of the Series B Milestone Event.
(iii) The earlier of (a) May 27, 2029 and (b) 60 days following the Series B Milestone Event.

NOTE 12 – SHARE-BASED COMPENSATION

a) **Equity Incentive Plan – general**

As of December 31, 2024, 6,900,704 Ordinary Shares were authorized for issuance to employees, directors and consultants under the 2019 Equity Incentive Plan (the "2019 Plan"), of which 2,121,494 shares were available for future grant.

Options granted under the 2019 Plan generally expire ten years following the date of grant. Upon termination of an award recipient's employment or other relationship with the Company, restricted shares and options cease vesting and unvested shares and options are forfeited. Forfeited shares and shares underlying forfeited or expired options become available for future grant under the 2019 Plan.

On February 15, 2024, the Board approved the extension of the term of the options to purchase Ordinary Shares that had been granted to serving directors, officers and employees of the Company during 2015 through 2019, so that such options shall expire on December 31, 2033. With respect to the Company's directors and the CEO, the extension was approved by the Company's shareholders on November 7, 2024. The Company recorded expenses of $564 thousand with respect to such option term extension.

b) **Stock option information**

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model using the following assumptions during the periods indicated:

	Year ended December 31,		
	2024	2023	2022
Weighted Average Risk-free interest rate	4.21%	4.65%	3.41%
Dividend yield	-	-	-
Weighted Average Volatility factor	89.73%	84.83%	91.62%
Weighted Average Expected life of the options	5	5	5

The following table contains additional information concerning options granted under the existing stock-option plan:

	For the year ended December 31,					
	2024		2023		2022	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of the year	2,842,496	$ 5.63	2,939,434	$ 5.85	2,142,547	$ 6.02
Granted	265,000	$ 3.11	53,192	$ 3.53	860,492	$ 5.49
Forfeited and expired	(209,481)	$ 6.05	(150,130)	$ 9.31	(40,730)	$ 6.42
Exercised	-	$ -	-	$ -	(22,875)	$ 6.49
Outstanding at end of the year	2,898,015	$ 5.37	2,842,496	$ 5.63	2,939,434	$ 5.85
Exercisable at end of the year	2,315,048	$ 5.46	2,245,993	$ 5.53	1,953,429	$ 5.55

Following is a summary of changes in nonvested shares granted:

	For the year ended December 31,					
	2024		2023		2022	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Balance at beginning of the year	596,503	$ 5.53	986,005	$ 6.46	529,082	$ 8.69
Granted	265,000	$ 3.11	53,192	$ 3.53	860,492	$ 5.49
Vested during the year	(233,473)	$ 5.88	(384,203)	$ 7.35	(370,839)	$ 7.14
Forfeited during the year	(45,063)	$ 4.43	(58,491)	$ 7.16	(32,730)	$ 6.43
Balance at end of the year	582,967	$ 4.38	596,503	$ 5.53	986,005	$ 6.46

The weighted-average fair values at grant date of options granted during the years ended December 31, 2024, 2023 and 2022 were $2.27, $3.53 and $5.49, respectively.

The total unrecognized estimated compensation cost related to non-vested stock options granted until December 31, 2024 was $636 thousand, which is expected to be recognized over a weighted average period of 1.49 years.

c) Set forth below is data regarding the range of exercise prices and remaining contractual life (in years) for options outstanding at December 31, 2024:

Exercise price	Number of options outstanding	Remaining contractual Life (in years)	Intrinsic Value of Options Outstanding (in thousands)	No. of options exercisable
$ 1.42	15,000	9.50	$ -	-
$ 2.69	90,304	2.18	-	90,304
$ 2.69	559,288	9.01	-	559,288
$ 3.21	224,000	9.13	-	-
$ 3.53	53,192	8.84	-	13,298
$ 3.66	250,000	5.34	-	250,000
$ 4.68	31,500	5.25	-	31,500
$ 5.34	152,250	7.25	-	78,500
$ 5.34	442,410	7.88	-	287,087
$ 5.97	150,000	7.88	-	75,000
$ 6.22	147,536	1.47	-	147,536
$ 6.22	332,110	9.01	-	332,110
$ 8.19	150,000	9.01	-	150,000
$ 9.02	40,500	5.87	-	40,500
$ 10.12	2,421	3.87	-	2,421
$ 10.12	6,534	9.01	-	6,534
$ 12.23	250,000	6.41	-	250,000
$ 21.40	970	9.01	-	970
	2,898,015		$ -	2,315,048

The total intrinsic value of options exercised during 2024 was $0.

d) The following table contains information concerning restricted stock units granted under the existing equity incentive plans:

	For the year ended December 31,					
	2024		2023		2022	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Nonvested at beginning of period	621,135	$ 3.14	157,560	$ 10.02	229,331	$ 10.08
Granted	825,687	$ 1.266	529,854	$ 1.90	-	$ -
Vested	(175,991)	$ 4.06	(52,521)	$ 10.05	(67,458)	$ 9.91
Forfeited	(36,259)	$ 2.75	(13,758)	$ 9.77	(4,313)	$ 14.67
Nonvested at end of period	1,234,572	$ 1.77	621,135	$ 3.14	157,560	$ 10.02

The Company estimates the fair value of restricted stock units based on the closing sales price of the Ordinary Shares on the date of grant (or the closing bid price if no sales were reported). For the years ended December 31, 2024, 2023 and 2022, the Company recognized $658 thousand, $481 thousand and $744 thousand, respectively, of share-based compensation expense related to restricted stock units. Total share-based compensation expense related to restricted stock units not yet recognized as of December 31, 2024 was $1,300 thousand, which is expected to be recognized over a weighted average period of 2 years.

e) The following table summarizes share-based compensation expenses related to grants under the 2019 Plan included in the statements of operations:

	Year ended December 31,		
(in thousands)	2024	2023	2022
Research & development	$ 916	$ 524	$ 876
General & administrative	1,149	1,427	1,836
Total	$ 2,065	$ 1,951	$ 2,712

NOTE 13 – TAXES ON INCOME

a. The Israeli corporate tax rate is 23%.

b. The Company has not paid income taxes since its incorporation. Tax assessments through the year ended December 31, 2018 are deemed to be final.

c. The Parent and its subsidiaries are taxed separately.

The Company measures its results for tax purposes in nominal terms in NIS based on financial reporting under Israeli accounting principles; therefore, there are differences between the Company's taxable income (loss) and income (loss) reflected in these financial statements.

As of December 31, 2024, the Parent had the following loss carry-forwards:

(i) Approximately $40 million deductible only against sale of assets and/or activities in connection with income generated from its clinical development programs prior to the Company's merger transaction in March 2019.

(ii) Approximately $19 million, arising after the Company's merger transaction in March 2019, deductible from future taxable income.

As of December 31, 2024, Enlivex Therapeutics R&D Ltd. and Enlivex Therapeutics RDO Ltd. had loss carry-forwards amounting to approximately $58 million and $1.7 million, respectively, deductible from future taxable income. These losses carry-forward have no expiration date.

d. The components of the provision for income taxes are as follows:

	Year ended December 31,		
(in thousands)	2024	2023	2022
Current tax	$ -	$ -	$ -
Deferred tax	-	-	-
Provision for income taxes, net	$ -	$ -	$ -

e. A reconciliation between the Company's effective tax rate and the statutory rate are as follows:

	Year ended December 31,		
	2024	2023	2022
Statutory tax rate	23%	23%	23%
Permanent differences	1%	1%	-%
Exchange rate differences	-%	(3)%	(3)%
Change in valuation allowance	(24)%	(21)%	(20)%
Effective tax rate	-	-	-

f. Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial purposes and the amounts used for income tax purposes.

As of December 31, 2024, the Company had provided a full valuation allowance in respect of deferred tax assets. Management currently believes that because the Company has a history of losses, it is more likely than not that the deferred tax regarding the loss carry-forward and other temporary differences will not be realized for the foreseeable future.

Components of the Company's deferred tax liabilities and assets are as follows:

	Year ended December 31,	
(in thousands)	2024	2023
Tax assets in respect of:		
Accrued employees' and directors' compensation	$ 324	$ 205
Stock based compensation	2,289	1,813
Research and development expenses	2,847	4,016
Fixed assets	137	159
Loss on disposal group of assets held for sale	177	710
Net loss carryforward	31,520	26,831
Total deferred tax assets	37,294	33,734
Less - valuation allowance	(37,294)	(33,734)
Deferred tax assets	$ -	$ -

NOTE 14 – BALANCES AND TRANSACTIONS WITH RELATED PARTIES

Related party balances and transactions, excluding compensation of members of management and the Board, were as follows:

a) Reported in the accompanying consolidated balance sheets -

	December 31,	
(in thousands)	2024	2023
Current Liabilities - Accounts payable trade	$ -	$ 25
Current Liabilities - Accrued expenses	$ -	$ 23

b) Related parties' transactions

	Year ended December 31,		
(in thousands)	2024	2023	2022
R&D services	$ 26	$ 862	$ 1,322

NOTE 15 – FAIR VALUE MEASUREMENT

The Company's financial assets measured at fair value on a recurring basis consisted of the following types of instruments as of December 31, 2024 and 2023:

	December 31, 2024			
(in thousands)	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 3,301	$ 3,301	$ -	$ -
Short term deposits	20,195	20,195	-	-
Restricted cash	430	430	-	-
Total financial assets	$ 23,926	$ 23,926	$ -	$ -

	December 31, 2023			
(in thousands)	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 813	$ 813	$ -	$ -
Short term deposits	26,507	26,507	-	-
Restricted cash	413	413	-	-
Total financial assets	$ 27,733	$ 27,733	$ -	$ -

NOTE 16 – ASSETS AND LIABILITIES CLASSIFIED AS HELD FOR SALE

The Company classified certain long-lived assets as held for sale as of December 31, 2024 and 2023 due to its plan to dispose of these assets.

During 2024, the Company decided to dispose of a group of assets consisting of the right of use asset of some of its leased property in Ness Ziona, the leasehold improvements installed in the property and certain laboratory equipment. See note 9 – Leases for additional information on the disposed right of use asset.

As of December 31, 2024, the Company had identified a potential purchaser and negotiated a potential transaction to sell these assets. The transaction was completed in the first quarter of 2025; therefore, the criteria for assets held-for-sale were satisfied as of December 31, 2024. For the year ended December 31, 2024, the Company recognized a loss of $487 thousand related to the group of assets held for sale.

On September 19, 2021, the Company entered into a lease agreement for a manufacturing plant space in Yavne, Israel for the purpose of manufacturing Allocetra™ to support ongoing clinical trials,. The lease provided for a term of 60 months with options for two successive 60-month extensions. The Company completed construction on the manufacturing plant in the fourth quarter of 2022. During 2023, the Company announced a strategic reprioritization plan, which included the sale of the plant and leasehold improvements installed in the plant and certain laboratory equipment. The group of assets and liabilities was classified as held for sale as of December 31, 2023, and the assets and liabilities were sold during 2024. The Company recognized losses on the disposed assets and liabilities of $470 thousand and $4,244 thousand for the years ended December 31, 2024 and 2023, respectively.

NOTE 17 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

a. Research and development expenses – net

	Year ended December 31,		
(in thousands)	2024	2023	2022
Payroll and related expenses	$ 3,078	$ 5,265	$ 6,371
Research and development services	5,039	9,853	8,264
Materials	553	1,880	2,044
Share Based Compensation	916	524	876
Depreciation	497	802	740
Other	540	911	1,605
	10,623	19,235	19,900
Israel Innovation Authority participation in research and development costs and royalties payable	-	(223)	(1,207)
	$ 10,623	$ 19,012	$ 18,693

b. General and administrative expenses

(in thousands)	Year ended December 31, 2024	2023	2022
Payroll expenses	$ 831	$ 912	$ 1,289
Compensation to directors	1,216	887	681
Professional fees	1,029	969	1,294
Office maintenance and office expenses	105	906	402
Insurance	351	567	895
Share Based Compensation	1,149	1,427	1,836
Other	232	471	707
	$ 4,913	$ 6,139	$ 7,104

c. Other expenses (income)

(in thousands)	Year ended December 31, 2024	2023	2022
Loss on disposal group of assets held for sale	$ 957	$ 4,244	$ -
Income from cancelation of uncertain tax positions	(605)	-	-
	$ 352	$ 4,244	$ -

d. Finance income (expenses), net

(in thousands)	Year ended December 31, 2024	2023	2022
Interest income	$ 1,069	$ 1,565	$ 835
(Loss) income related to marketable securities	-	-	(1,983)
Exchange differences, net	(182)	(1,224)	(4,101)
Bank commissions and other expenses	(13)	(14)	(14)
	$ 874	$ 327	$ (5,263)

NOTE 18 – EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE

1. During the first quarter of 2025 the Company issued and sold 164,656 Ordinary Shares under the ATM Agreement.

2. On January 29, 2025 the Company completed the sale of a group of assets consisting of the right of use asset of some of its leased property in Ness Ziona, the leasehold improvements installed in the property and certain laboratory equipment. See note 16.

THIRD AMENDMENT TO
CONSULTING AGREEMENT

THIS THIRD AMENDMENT (the "**Third Amendment"**) is entered into as of November 7, 2024, by and between **Enlivex Therapeutics, Ltd.**, a company organized under the laws of the State of Israel, corporate number 51373620, whose address is at 14 Einstein Street, Ness Ziona, Israel 7403618 (the **"Company"**) and **A.S. Novik Ltd.,** a company organized under the laws of the State of Israel, corporate number 513439273, whose address is 30 Anni Maamin Street, Ramat Hasharon, Israel 4721249 (the "**Consultant**").

WHEREAS, the Company and the Consultant have entered into that certain agreement dated September 7, 2018, as amended on June 24, 2020 and November 4, 2021 (collectively, the "**Consulting Agreement**"), pursuant to which Mr. Shai Novik provides Executive Chairman services to the Company. *All capitalized terms used but not otherwise defined herein shall have the same meaning ascribed to such terms in the Consulting Agreement*; and

WHEREAS, the Company and Consultant have agreed to amend certain terms of the Consultant Agreement as set forth below.

NOW THEREFORE, in consideration of their mutual covenants and agreements hereinafter set forth, the parties hereto hereby agree as follows:

1. Amendments to Consulting Agreement.

The parties have agreed to the following amendments to the Consulting Agreement, effective as of January 1, 2024:

1.1. Section 3(a) of the Consulting Agreement ("*Base Retainer*") shall be amended and replaced in its entirety by the following:

> "**(a) Base Retainer.** Consultant shall receive an aggregate annual minimum base retainer at the rate of Four Hundred and Twenty Thousand Dollars ($420,000), payable in equal monthly installments of $35,000 (the "**Base Retainer**"). Payments of the Base Retainer shall be made in New Israeli Shekels ("**NIS**") in accordance with the terms set forth in Section 3(f) hereinbelow."

1.2. Section 3(f) of the Consulting Agreement ("*Payment in NIS*") shall be amended and replaced in its entirety by the following:

> "(f) **Payments in NIS**. All amounts payable to Consultant pursuant to this Agreement, including the dollar amounts enumerated in Section 3(a) ("Base Retainer") and (d) ("Reimbursement of Expenses"), shall be paid to the Consultant in NIS, based on a U.S. dollar/NIS exchange rate equal to the higher of: (i) the then prevailing U.S. dollar/NIS exchange rate and (ii) USD 1 = NIS 3.581."

2. General.

2.1. Except as explicitly stated herein, all other terms and conditions of the Consulting Agreement shall remain in effect and unchanged.

2.2. This Amendment shall be read together with the Consulting Agreement, and shall constitute an integral part thereof, and, save as expressly amended by this Amendment, the Consulting Agreement shall remain unaltered and in full force and effect.

2.3. This Amendment constitutes the final, complete and exclusive agreement of the parties with respect to the subject matter hereof and supersedes and merges all prior discussions or agreements between the parties with respect to the subject matter hereof. No modification of or amendment to the Consulting Agreement as amended by this Amendment, nor any waiver of any rights under this Amendment, will be effective unless in writing and signed by both parties hereto.

2.4. In the event of any ambiguity or discrepancy between the provisions of this Amendment and any of the Consulting Agreement, the terms of this Amendment with respect to those provisions described herein shall prevail.

2.5. This Amendment and the Consulting Agreement shall be governed, construed and enforced in accordance with, the laws of the State of Israel. The competent courts in the District of Tel Aviv, Israel shall have exclusive jurisdiction in all matters arising out of or in connection with the Consulting Agreement, as amended hereby.

2.6. This Amendment may be executed in multiple counterparts (including by electronic transmission in portable document format (pdf)), any one of which need not contain the signature of more than one party, but all such counterparts taken together will constitute one and the same instrument

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IN WITNESS WHEREOF, each of the parties hereto has caused this Third Amendment to be executed, all as of the day and year first above written.

ENLIVEX THERAPEUTICS, LTD.

/s/ Shachar Shlosberger
By: Shachar Shlosberger
Title: CFO

A.S. NOVIK LTD.

/s/ Shai Novik
By: Shai Novik
Title: Director

[Signature Page to Amendment to Agreement]

Exhibit 8.1

SUBSIDIARIES OF ENLIVEX THERAPEUTICS LTD.

At December 31, 2024	Country/State	Percentage of voting share capital held
Wholly owned subsidiaries		
Enlivex Therapeutics R&D Ltd.	Israel	100
Enlivex Therapeutics Inc. (f/k/a Bio Blast Pharma, Inc.)	Delaware	100
Enlivex Therapeutics RDO Ltd.	Israel	100

Exhibit 11.1

ENLIVEX THERAPEUTICS LTD.

INSIDER TRADING POLICY
AND GUIDELINES WITH RESPECT TO
CERTAIN TRANSACTIONS IN COMPANY SECURITIES

Date: June 23, 2015

This Insider Trading Policy (the "**Policy**") provides guidelines to directors, officers, employees and other related individuals of Enlivex Therapeutics Ltd, an Israeli company (the "**Company**"), with respect to transactions in the Company's securities. The Company has adopted this Policy in order to ensure compliance with securities laws and to avoid even the appearance of improper conduct by anyone associated with the Company. Failure to comply with these procedures could result in a serious violation of the securities laws by you and/or the Company and can result in both civil penalties and criminal fines and imprisonment. We have all worked hard to establish the Company's reputation for integrity and ethical conduct, and we are all responsible for preserving and enhancing this reputation. The appearance of insider trading can cause a substantial loss of confidence in the Company and its shares on the part of the public and the securities markets. This could result in an adverse impact on the Company and its shareholders. Accordingly, avoiding the appearance of engaging in share transactions on the basis of material undisclosed information can be as important as avoiding a transaction actually based on such information. The Company has appointed its Chief Financial Officer (the "**CFO**") as the Company's Insider Trading Compliance Officer.

I. Applicability of Policy

This Policy applies to all transactions in the Company's securities, including common stock, options and any other securities the Company may issue from time to time, such as preferred shares, warrants, notes, and convertible debentures, as well as to derivative securities relating to the Company's shares, whether or not issued by the Company, such as exchange-traded options and debt securities. It applies to all officers of the Company, all members of the Company's Board of Directors, and all employees of, and consultants and contractors to, the Company and its subsidiaries/branches who receive or have access to Material Nonpublic Information (as defined below) regarding the Company (collectively, "Company Affiliated Persons"). Company Affiliated Persons, members of their immediate families (which include spouse and minor children), members of their households, other family members living with them or who are supported by them, are sometimes referred to in this Policy as "Insiders". This Policy also applies to any trust or other estate in which an Insider has a substantial beneficial interest or as to which he or she serves as trustee or in a similar fiduciary capacity, and to any trust, corporation, partnership or other entity which the Insider controls, including venture capital partnerships. This Policy also applies to any person who receives Material Nonpublic Information from any Insider.

Any person who possesses Material Nonpublic Information regarding the Company is an Insider for so long as the information is not publicly known. Any employee can be an Insider from time to time, and would at those times be subject to this Policy.

The Policy imposes additional restrictions upon Insiders who have routine access to Material Nonpublic Information, referred to as "Access Insiders." Access Insiders are: (1) members of the board of directors, (2) the executive officers, (3) the controller, and (4) the investor relations department of the Company**.** In addition, other employees of the Company who have routine access to Material Nonpublic Information as determined by the CFO, who were notified that these additional restrictions apply to them shall also be Access Insiders until otherwise determined by the CFO.

II. General Policy

It is the policy of the Company to oppose the unauthorized disclosure of any nonpublic information acquired in the work-place and the misuse of Material Nonpublic Information in securities trading.

III. Specific Policies

1. Trading on Material Nonpublic Information. No Insider shall engage in any transaction involving a purchase or sale of the Company's securities, including any offer to purchase or offer to sell, during any period commencing with the time that he or she first receives Material Nonpublic Information concerning the Company, and ending at the close of business on the second Trading Day following the date of public disclosure of that information, or at such time as such nonpublic information is no longer material. As used herein, the term "**Trading Day**" shall mean a day on which the NASDAQ Capital Market is open for trading.

2. Tipping. No Insider shall disclose (sometimes called a "**Tip**") Material Nonpublic Information to any other person (including family members) where such information may be used by such person to his or her profit by trading in the securities of companies to which such information relates, nor shall such Insider or related person make recommendations or express opinions on the basis of Material Nonpublic Information as to trading in the Company's securities.

3. Confidentiality of Nonpublic Information. Nonpublic information relating to the Company is the property of the Company and the unauthorized disclosure of such information is forbidden. In the event any officer, director or employee of the Company receives any inquiry from outside the Company, such as a stock analyst, for information (particularly financial results and/or projections) that may be Material Nonpublic Information, the inquiry should be referred to the CFO, and to the other appropriate Company officers, as provided for in the Disclosure Policy of the Company.

IV. Potential Criminal and Civil Liability and/or Disciplinary Action

1. Liability for Insider Trading. In the United States and many other countries, the personal consequences to an Insider of illegally trading securities while in possession, or on the basis of, Material Nonpublic Information can be quite severe. In the United States there are substantial civil penalties and criminal sanctions which may be assessed for insider trading. Civil penalties are a payment of a penalty of up to three times the illicit windfall. In addition, Insiders may be subject to criminal fines of up to $5,000,000 and up to twenty years in prison for engaging in transactions in the Company's securities at a time when they have knowledge of Material Nonpublic Information regarding the Company.

If you are located or engaged in dealings outside the U.S., be aware that laws regarding insider trading and similar offenses differ from country to country. Employees must abide by the laws in the country where located. However, you are required to comply with this Policy even if local law is less restrictive. If a local law conflicts with this Policy, you must consult the CFO.

If securities transactions ever become the subject of scrutiny, they are likely to be viewed after-the-fact with the benefit of hindsight. As a result, before engaging in any transaction an Insider should carefully consider how the transaction may be construed in the bright light of hindsight. If you have any questions or uncertainties about this Policy or a proposed transaction, please ask the CFO.

2. Liability for Tipping. Insiders may also be liable for improper transactions by any person (commonly referred to as a "**Tippee**") to whom they have disclosed Material Nonpublic Information or any person to whom the Tippee discloses such Material Nonpublic Information regarding the Company or to whom they have made recommendations or expressed opinions on the basis of such information as to trading in the Company's securities. The civil penalties and criminal sanctions for tipping by an Insider are the same as the ones for an Insider conducting insider trading, even if the disclosing person did not profit from the trading. The U.S. Securities and Exchange Commission (the "SEC"), the Financial Industry Regulatory Authority ("**FINRA**") and the stock exchanges use sophisticated electronic surveillance techniques to uncover insider trading.

3. Possible Disciplinary Actions. The seriousness of securities law violations is reflected in the penalties and criminal sanctions such violations carry. These violations may also create negative publicity for the Company and a director's resignation may be sought, or an officer or other employee will be subject to possible Company disciplinary action including ineligibility for future participation in the Company's equity incentive plans or termination of employment.

V. Individual Responsibility

Every Company Affiliated Person has the individual responsibility to comply with this Policy against insider trading, regardless of whether the Company has recommended a trading window to that person or any other Insiders of the Company. The guidelines set forth in this Policy are not intended to provide a conclusive solution for all circumstances, and appropriate judgment should be exercised in connection with any trade in the Company's securities.

An Insider may, from time to time, have to forego a proposed transaction in the Company's securities even if he or she planned to make the transaction before learning of the Material Nonpublic Information and even though the Insider believes he or she may suffer an economic loss or forego anticipated profit by waiting.

VI. Applicability of Policy to Inside Information Regarding Other Companies

This Policy and the guidelines described herein also apply to Material Nonpublic Information relating to other companies, including the Company's customers, vendors or suppliers ("**Business Partners**"), when that information is obtained in the course of employment with, or other services performed on behalf of, the Company. Civil penalties and criminal sanctions, and termination of employment, may result from trading on inside information regarding the Company's Business Partners. All employees should treat Material Nonpublic Information about the Company's Business Partners with the same care required with respect to information related directly to the Company.

VII. Dissemination of Company Information

The prohibition of the disclosure of Material Nonpublic Information applies to all contacts made within and outside the Company. Care should be taken to prevent the disclosure of Material Nonpublic Information during all contact including phone calls and casual conversation. If in doubt about whether information falls into the category of Material Nonpublic Information, then the information should not be disclosed.

Prior to disclosure to any third party, any officer, director or employee of the Company who is aware of any Material Nonpublic Information concerning the Company that has not been disclosed to the public should report the intention to disclose such information promptly to the CFO and obtain approval to do so, or otherwise act in accordance with the Company's Disclosure Policy.

VIII. Definition of Material Nonpublic Information

Material Nonpublic Information is information which is material, and that has not been disclosed or otherwise made available to the general public by the Company.

It is not possible to define all categories of material information. Generally, information should be regarded as material if a reasonable investor would consider it important in making an investment decision regarding the purchase or sale of the Company's securities or the information, if made public, would likely affect the market price of the Company's securities. Either positive or negative information may be material. Information may be material even if it relates to future, speculative or contingent events and even if it is significant only when considered in combination with publicly available information. Nonpublic information can be material even with respect to companies that do not have publicly traded stock, such as those with outstanding bonds or bank loans.

While it may be difficult under this standard to determine whether particular information is material, there are various categories of information that are particularly sensitive and, as a general rule, should always be considered material. If any Insider has questions as to the materiality of information, he or she should contact the CFO for clarification. Examples of information which is deemed to be material include:

- Financial results;
- Projections of future earnings or losses;
- News of a pending or proposed merger or acquisition;
- New product or project announcements of a significant nature;
- Expansion or curtailment of operations or the gain or loss of a substantial customer;
- The initiation, suspension and results of the Company's clinical trials and any other material information relating thereto;
- Changes in control of the Company or major changes in senior management;
- Significant new joint ventures, alliances, or strategic partnerships or material developments in existing arrangements;
- Impending bankruptcy or financial liquidity problems;
- Significant product defects or modifications;

- Significant pricing changes;
- Events regarding the Company's securities (e.g. stock splits, repurchases, or changes in dividend policy);
- Changes in auditors or auditor notification that the Company may no longer rely on an audit report;
- A significant purchase or sale of assets or disposition of a subsidiary or division;
- New equity or debt offerings, significant borrowings, or other material financial transactions;
- Significant litigation exposure due to actual or threatened litigation;
- Significant actions by regulatory bodies;
- Receipt, cancellation or deferral of significant purchase orders;
- Significant actions by regulatory bodies;
- Proposed payment of a dividend; and
- Any of the above with respect to a subsidiary, or other affiliate of the Company.

Nonpublic information is information that has not been previously disclosed to the general public and is otherwise not available to the general public. It is important to note that information is not necessarily public merely because it has been discussed in the press, which will sometimes report rumors. You should presume that information is nonpublic unless you can point to its official release by the Company in at least one of the following ways:

1. Information contained in publicly available documents filed with securities regulatory authorities (e.g., filings with the SEC);
2. Issuance of press releases; or
3. Meetings with members of the press and the public.

IX. Additional Circumstances Where No Exceptions Apply

There are almost no exceptions to the prohibition against insider trading. For example, it does not matter that the transactions in question may have been planned before the Insider came into possession of the undisclosed material information, regardless of the economic loss that the person may believe he or she might suffer as a consequence of not trading.

As noted above, the definition of Insiders, to which this Policy applies, includes immediate family members of Company Affiliated Persons. Although immediate family is narrowly defined, a Company Affiliated Person should be especially careful with respect to family members or to unrelated persons living in the same household.

Finally, there are no limits on the size of a transaction that will trigger insider trading liability; relatively small trades have in the past occasioned investigations and lawsuits.

X. Trading Window

The period beginning two weeks before the end of the last month of each calendar quarter and ending two Trading Days following the date of public disclosure of the financial results for that quarter, is a particularly sensitive period of time for transactions in the Company's shares from the perspective of compliance with applicable securities laws. This sensitivity is due to the fact that directors, officers and certain other employees will, during that period, often possess Material Nonpublic Information about the expected financial results for the quarter.

Accordingly, to ensure compliance with this Policy and applicable federal and state securities laws, it is the Company's policy that all directors, officers and employees refrain from conducting transactions involving the purchase or sale of the Company's securities other than during the period (the "**Trading Window**") commencing at the close of business on the second Trading Day following the date of public disclosure of the financial results for a particular fiscal quarter or year and continuing until the day that is two weeks before the last day of the last month of the next fiscal quarter. As a courtesy to the persons subject to this Policy, the Company may provide advance notice before the Trading Window opens.

From time to time, the Company may also notify that directors, officers, selected employees and others are required to suspend trading because of developments known to the Company and not yet disclosed to the public. In such event, such persons are advised not to engage in any transaction involving the purchase or sale of the Company's securities during such period and should not disclose to others the fact of such suspension of trading.

The purpose behind the self-imposed Trading Window period is to help establish a diligent effort to avoid any improper transaction. It should be noted, however, that even during the Trading Window, any person possessing Material Nonpublic Information concerning the Company may not attempt to "beat the market" by trading simultaneously with, or shortly after, the official release of Material Nonpublic Information. Although there is no fixed period for how long it takes the market to absorb information, out of prudence a person aware of Material Nonpublic Information should refrain from any trading activity for at least two full Trading Days following its official release, whether or not the Company has recommended a suspension of trading to that person.

NOTWITHSTANDING THESE TIMING GUIDELINES, IT IS ILLEGAL FOR ANY PERSON TO TRADE WHILE IN POSSESSION OF MATERIAL NONPUBLIC INFORMATION, INCLUDING SITUATIONS IN WHICH THE PERSON IS AWARE OF MAJOR DEVELOPMENTS THAT HAVE NOT YET BEEN PUBLICLY ANNOUNCED BY THE COMPANY. TRADING IN THE COMPANY'S SECURITIES DURING THE TRADING WINDOW SHOULD NOT BE CONSIDERED A "SAFE HARBOR," AND ALL DIRECTORS, OFFICERS AND OTHER INSIDERS SHOULD USE GOOD JUDGMENT AT ALL TIMES.

XI. Inquiries

All Insiders should review this Policy carefully and contact the CFO if they have a concern that a contemplated transaction in the Company's securities might not conform with this Policy.

XII. Certain Exceptions

For purposes of this Policy, the Company considers that the exercise of share options for cash under the Company's share option plans or the purchase of shares under employee purchase plans that may be adopted in the future (but not the sale of any such shares) is exempt from this Policy, since the other party to the transaction is the Company itself and the price does not vary with the market but is fixed by the terms of the option agreement or the plan. Accordingly, cashless exercises of options are subject to the Policy when they involve the sale of shares into the public marketplace.

Bona fide gifts of securities are not deemed to be transactions for the purposes of this Policy. Whether a gift is truly bona fide will depend on the circumstances surrounding each gift. The more unrelated the donee is to the donor, the more likely the gift would be considered "bona fide" and not a "transaction". For example, gifts to charities, religious institutions and service organizations would likely not be "transactions". On the other hand, gifts to dependent children followed by a sale of the "gift" securities in close proximity to the time of the gift may imply some economic benefit to the donor and, therefore, make the gift non-bona fide.

The restrictions in this Policy shall not apply to purchases or sales made pursuant to a Qualified Plan. For purposes of this exception, a "**Qualified Plan**" is a written plan for purchasing or selling the Company's securities which meets each of the following requirements: (1) the plan is adopted by the Insider during a Trading Window; (2) the plan is adopted in good faith by the Insider when he or she is not in possession of material non-public information; (3) the plan is adhered to strictly by the Insider; (4) the plan either (a) specifies the amount of securities to be purchased or sold and the date on which the securities are to be purchased or sold, (b) includes a written formula or algorithm, or computer program, for determining the amount of securities to be purchased or sold and the price at which and the date on which the securities are to be purchased or sold, or (c) does not permit the Insider to exercise any subsequent influence over how, when, or whether to effect purchases or sales; provided, in addition, that any other person who, pursuant to the plan, does exercise such influence must not have been aware of the material nonpublic information when doing so; and (5) at the time it is adopted the plan conforms to all other requirements of Rule 10b5- 1(c)(1)(C) under the U.S. Securities Exchange Act of 1934 as then in effect.

In addition to the above requirements, a Qualified Plan shall be signed and dated by the Insider, and submitted to the CFO at least two (2) trading days before it is filed with the broker who executes it. The Company shall have the right, at all time, to suspend purchases or sales under a Qualified Plan, for instance in the event that the Company needs to comply with requirements by underwriters for "lock-up" agreements in connection with an underwritten public offering of the Company's securities. A Qualified Plan cannot be canceled, suspended, expanded or otherwise modified by the Insider who signed it more than once during a fiscal quarter. Any cancellation, suspension, expansion or other modification of a Qualified Plan by the Insider who established it must: (1) be in writing, signed and dated by such Insider, (2) be submitted to the CFO within two (2) trading days after the cancellation, suspension, expansion or other modification was reduced to writing, and (3) be made during a Trading Window, and when the Insider who established it has no Nonpublic Material Information about the Company.

XIII. Additional Information for Directors, Officers and Certain Employees with Routine Access to Material Nonpublic information

This Policy imposes additional restrictions upon Access Insiders, because of their routine access to Material Nonpublic Information.

1. Preclearance of Trades. The Company has determined that all Access Insiders should refrain from trading in the Company's securities, even during the Trading Window, without first complying with the Company's "preclearance" process. Each Access Insider should contact the CFO prior to commencing any trade in the Company's securities. At the time of executing a trade in the Company's securities, such individuals will be responsible for verifying that the Company has not imposed any restrictions on their ability to engage in trades. If the individual has not completed the trade within ten (10) trading days of notification of the intention to trade, then the individual must again notify the CFO that he or she intends to execute a trade and re-verify the nonexistence of any restrictions on such trade. For the avoidance of doubt, this paragraph shall not apply to a Qualified Plan, after it has been set up.

Before each transaction in the Company's securities by a Company each officer and director should contact the CFO regarding compliance with Rule 144 of the U.S. Securities Act of 1933, as amended ("**Rule 144**"), which contains guidelines for the sale of privately issued shares and sales by affiliates of the Company, if such sales are not covered by an effective registration statement, to the extent applicable.

2. Rule 144 and Section 16 Matters for Directors and Officers. Directors and principal officers of the Company must also comply with Rule 144, or another applicable exemption from registration. The practical effect of Rule 144 is that directors and officers who sell the Company's securities may be required to comply with a number of requirements including holding period, volume limitation, manner of sale and SEC filing requirements. The Company may provide separate memoranda and other appropriate materials to its directors and officers regarding compliance with Rule 144. In addition, if the Company is no longer considered a "foreign private issuer", the directors and officers who trade with Company securities have to report of purchases and sales of shares through the filing of Form 4 with the U.S. Securities and Exchange Commission. The Company will advise such persons if they are subject to the requirement to file a Form 4.

XIV. Specific Requirements

1. **Speculative Trading**. No Insider may engage in transactions of a speculative nature at any time. All Insiders are prohibited from short-selling the Company's securities or engaging in transactions involving the Company's based derivative securities. A short sale, for these purposes, means any transaction whereby one may benefit from a decline in the price of the Company's securities. "**Derivative Securities**" are options, warrants, stock appreciation rights or similar rights whose value is derived from the value of an equity security, such as the Company's common stock. This prohibition includes, but is not limited to, trading in the Company's based put and call option contracts, transacting in straddles, hedging or monetization transaction with respect to the Company's securities, and the like. In addition, no Insider shall engage in a transaction with respect to securities of the Company if he or she owns the security, but does not deliver it against such sale (a "short sale against the box") within twenty days thereafter, or does not within five days after such sale deposit it in the mails or other usual channels of transportation. The above does not derogate from Insiders' right to hold and exercise options or other derivative securities granted under the Company's employee share option or equity incentive plans as long as such exercise is not prohibited by this Policy.

2. **Post-Termination Transactions.** If an Insider is aware of Material Nonpublic Information at the time such Insider's association with the Company is terminated, whether by the Insider or the Company, the Insider may not trade in Company securities until such information is no longer material or until two Trading Days after such information has become public. In addition, if the Company is not in a Trading Window at the time such association with the Company is terminated, the Insider may not trade in Company securities until two Trading Days after the next announcement of quarterly earnings or of the material, non-public information.

3. **Ad hoc Restrictions**. The CFO has the authority to impose restrictions on trading in the Company's securities by appropriate individuals at any time. In such event, the CFO will notify the affected individuals, either personally, by email or by voicemail, to inform them of the restrictions.

4. **Open Orders**. Any Insider who has placed a limit order or open instruction to buy or sell the Company's securities shall bear responsibility for canceling such instructions immediately upon becoming in possession of Material Nonpublic Information.

XV. Acknowledgement

Please sign the attached acknowledgement form and return it to the CFO.

If you have any questions with respect to this Policy, please contact the Company's Chief Financial Officer.

ACKNOWLEDGEMENT

I have received, read and understand the Insider Trading Policy and Guidelines with Respect to Certain Transactions in Company Securities of Enlivex Therapuetics Ltd., a copy of which is attached hereto, and agree to comply with the provisions thereof.

Date: _____

_____
Signature

_____
Name

_____
Title

Exhibit 12.1

CERTIFICATION PURSUANT TO
EXCHANGE ACT RULE 13a-14(a) or 15d-14(a)

I, Dr. Oren Hershkovitz, certify that:

1. I have reviewed this Annual Report on Form 20-F of Enlivex Therapeutics Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the company and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 30, 2025

/s/ Oren Hershkovitz
Oren Hershkovitz
Chief Executive Officer

Exhibit 12.2

CERTIFICATION PURSUANT TO
EXCHANGE ACT RULE 13a-14(a) or 15d-14(a)

I, Shachar Shlosberger, certify that:

1. I have reviewed this Annual Report on Form 20–F of Enlivex Therapeutics Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the company and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 30, 2025

/s/ Shachar Shlosberger
Shachar Shlosberger
Chief Financial Officer

Exhibit 13.1

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350

In connection with the filing of the Annual Report on Form 20–F for the period ended December 31, 2024 (the "Report") by Enlivex Therapeutics Ltd. (the "Company"), the undersigned, as the Chief Executive Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Oren Hershkovitz
Oren Hershkovitz
Chief Executive Officer

April 30, 2025

Exhibit 13.2

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350

In connection with the filing of the Annual Report on Form 20–F for the period ended December 31, 2024 (the "Report") by Enlivex Therapeutics Ltd. (the "Company"), the undersigned, as the Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Shachar Shlosberger
Shachar Shlosberger
Chief Financial Officer

April 30, 2025

Exhibit 15.1

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statement on Forms S-8, F-3 and F-3MEF (File No. 333-256799, File No. 333-232413, File No. 333-232009, File No. 333-252926 and File No. 333-264561) of Enlivex Therapeutics Ltd. of our report dated March 31, 2025 with respect to the consolidated financial statements and the effectiveness of internal control over financial reporting of Enlivex Therapeutics Ltd. included in this Report on Form 20-F of Enlivex Therapeutics Ltd. filed with the Securities and Exchange Commission.

/s/ Yarel + Partners

Tel- Aviv, Israel
April 30, 2025