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

Form 10-K

(Mark One)

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

For the fiscal year ended **December 31, 2022**

or

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

For the transition period from _____ to ____.

Commission file number **001-36581**

Vascular Biogenics Ltd.
(Exact name of registrant as specified in its charter)

Israel	**Not applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
8 HaSatat St. Modi'in, Israel	**7178106**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **+972-8-9935000**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, par value NIS 0.01 per share	**VBLT**	**The Nasdaq Capital Market**

Securities registered pursuant to Section 12(b) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, 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. ☐

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's ordinary shares held by non-affiliates of the registrant, based on the closing price of the ordinary shares on the Nasdaq Global Market was approximately $93.8 million.

The number of registrant's ordinary shares outstanding as of March 13, 2023 was 69,750,117.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements that relate to future events or our future financial performance, which express the current beliefs and expectations of our management. Such statements involve a number of known and unknown risks, uncertainties and other factors that could cause our actual future results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Forward-looking statements include all statements that are not historical facts and can be identified by words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "could," and similar expressions or phrases. We have based these forward-looking statements largely on our management's current expectations and future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Forward-looking statements include, but are not limited to, express or implied statements about:

- the completion of the proposed merger, or the Merger, with Notable Labs, Inc. or Notable;
- implementation of our organizational streamlining and workforce reduction and anticipated savings therefrom;
- our cash runway;
- exploration of additional strategic transactions to further maximize shareholder value, including benefits from the sale of our rights to lease the Modi'in manufacturing facility and certain related assets;
- receipt of additional grant funding from the European Innovation Council, or EIC, accelerator program;
- effects of discontinuation of the OVAL trial and ofra-vec program in all indications;
- the initiation, timing, progress and results of our preclinical and clinical activities, including the first-in-human Phase 1 trial for VB-601 and our research and development program, if at all;
- our expectations about the availability and timing of data from any clinical trial;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our plans for future clinical trials;
- our ability to manufacture our product candidate in sufficient quantities for clinical trials and, if appropriate, commercialization;
- the timing or likelihood of regulatory filings and approvals, including data required to file for regulatory approval;
- the commercialization of our product candidate, if approved;
- potential advantages of our product candidate;
- the pricing and reimbursement of our product candidate, if approved;
- our ability to develop and commercialize additional product candidates based on our platform technology;
- our business strategy;
- the implementation of our business model, strategic plans for our business, product candidate and technology;
- the scope and duration of protection we are able to establish and maintain for intellectual property rights covering our product candidate and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to establish and maintain collaborations and the benefits of such collaborations;
- our ability to maintain our level of grant funding or obtain additional grant or other non-dilutive sources of funding;
- developments relating to our competitors and our industry; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

All forward-looking statements involve risks, assumptions and uncertainties. You should not rely upon forward-looking statements as predictors of future events. The occurrence of the events described, and the achievement of the expected results, depend on many events, some or all of which are not predictable or within our control. Actual results may differ materially from expected results. See "Item 1A. Risk Factors," "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report for a more complete discussion of these risks, assumptions and uncertainties and for other risks and uncertainties. These risks, assumptions and uncertainties are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results.

All of the forward-looking statements we have included in this Annual Report are based on information available to us on the date of this Annual Report. We undertake no obligation, and specifically decline any obligation, to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Annual Report might not occur.

SUMMARY OF RISK FACTORS

Investing in our common shares involves a high degree of risk. You should carefully consider the risks summarized below and other risks that we face, a detailed discussion of which can be found under "Item 1A. Risk Factors" below, together with other information in this annual report on Form 10-K and our other filings with the Securities and Exchange Commission, or SEC. This summary list of risks is not exhaustive of the factors that may affect any of our forward-looking statements and our business and financial results. If any of these risks actually occur, our business, financial condition and financial performance would likely be materially adversely affected. In such case, the trading price of our common shares would likely decline and you may lose part or all of your investment. Below is a summary of some of the principal risks we face:

- There is no assurance that the proposed Merger will be completed in a timely manner or at all. If the proposed Merger is not consummated, our business could suffer materially and our stock price could decline.
- If the proposed Merger is not completed, we may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the proposed Merger with Notable, or at all, and we may otherwise be unable to continue to operate our business. Our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our shareholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- The issuance of our ordinary shares to Notable stockholders in the proposed merger will substantially dilute the voting power of our current shareholders.
- We are exploring strategic alternatives to enhance shareholder value, including the proposed merger with Notable, transactions involving VB-601 and the recently completed sale of our Modi'in facility rights. We may not be successful in consummating such transactions or they may not deliver the value to our shareholders that we anticipate.
- Historically, we have been highly dependent on the success of ofra-vec in oncology applications. The Phase 3 OVAL clinical trial evaluating ofra-vec in ovarian cancer has been discontinued after not meeting statistical significance in progression-free survival, or PFS, or overall survival, or OS, and we have ceased further development of ofra-vec in all indications. Such failure and discontinued internal development of ofra-vec has resulted in, and may result in future, workplace reduction measures, decrease anticipated near-term revenues and profitability, may cause reputational harm and result in a wind down of our operations.
- We are not in compliance with the Nasdaq's minimum bid price requirement and if we fail to regain compliance with Nasdaq's continued listing requirements (or if the merger is completed and the combined company does not meet Nasdaq's initial listing requirements), our ordinary shares could be delisted, which could adversely affect the liquidity of our ordinary shares and our ability to raise additional capital or enter into strategic transactions.
- We have undergone a significant workforce reduction to reduce operating expenses and extend our cash runway, but such efforts may not yield the anticipated benefits, which could have a material effect on our operations.
- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- We have never generated any revenue from product sales and may never be profitable.
- We may need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations (or could impact our ability to complete the proposed merger or the equity split in the proposed merger).
- We have received and may continue to receive Israeli or other governmental grants to assist in the funding of our research and development activities. If we lose our funding from these research and development grants and do not receive new grants, we may encounter difficulties in the funding of future research and development projects and implementing technological improvements, which would harm our operating results.
- We may not receive the full €2.5 million grant from the Horizon Europe EIC Accelerator Program, which funding is subject to a lengthy process prior to receipt and which we may not successfully achieve, particularly in light of our decision to terminate the ofra-vec program and pursue the merger with Notable.
- We are highly dependent on our technology in general, and we cannot be certain that our product candidate VB-601 will receive regulatory approval or be commercialized or that we will be able to realize any value from VB-601. Any failure to successfully develop, obtain regulatory approval for and commercialize any current or future product candidates, independently or in cooperation with a third party collaborator, or the experience of significant delays in doing so, would compromise our ability to generate revenue and become profitable.
- Our product candidate VB-601 is based on novel technology and is in very early stages of development, which makes it difficult to predict the time and cost of development and potential regulatory approval.
- We may find it difficult to enroll patients in future clinical trials, and patients could discontinue their participation in our clinical trials, which could delay or prevent clinical trials of our product candidate.
- We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

- The results from our future clinical trials may not be sufficiently robust to support the submission for marketing approval for our product candidate. Before we submit our product candidates for marketing approval, the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, may require us to conduct additional clinical trials, or evaluate subjects for an additional follow-up period.
- Legislative and regulatory activity may exert downward pressure on potential pricing and reimbursement for our product candidate, if approved, that could materially affect the opportunity to commercialize.
- We expect to rely on third parties to conduct some or all aspects of our product manufacturing, protocol development, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.
- We intend to rely on third-party manufacturers to produce commercial quantities of any of our product candidates that receive regulatory approval, but we have not entered into binding agreements with any such manufacturers to support commercialization. Additionally, these manufacturers do not have experience producing our product candidate at commercial levels and may not pass regulatory inspections or achieve the necessary regulatory approvals or produce our product candidate at the quality, quantities, locations and timing needed to support commercialization.
- Our future success depends on our ability to retain key employees, consultants, and advisors and to attract, retain and motivate qualified personnel.
- Pandemics or other global emergencies could have an adverse impact on our developmental programs and our financial condition.
- The market price of our ordinary shares may be highly volatile, and you may not be able to resell your shares at the purchase price.
- As of January 1, 2023, we lost our foreign private issuer status, and we are required to comply with (1) the Exchange Act's domestic reporting regime and (2) accepted governance practices associated with U.S. domestic issuers in accordance with various SEC and Nasdaq rules, which will likely cause us to incur significant legal, accounting and other expenses. We also now qualify as a "smaller reporting company" and intend to use the scaled disclosures available to such companies, which may make an investment in our company less attractive to some investors.

PART I

Item 1. BUSINESS

Overview

We are a biopharmaceutical company that has historically focused on developing targeted therapies for immune-inflammatory diseases and cancer. Our goal has been to provide differentiated targeted therapeutics to address the underlying cause of diseases where treatment options are limited.

Our sole product candidate, VB-601, is a targeted antibody for immune-inflammatory applications that has shown disease-modifying activity across multiple preclinical models including multiple sclerosis, rheumatoid arthritis and inflammatory bowel disease. VB-601 was developed using our monocyte targeting technology, or MTT, and is designed to specifically inhibit monocyte migration. In October 2022, we submitted an application to the Israel Ministry of Health and institutional review board for a first-in-human Phase 1 trial evaluating VB-601 in healthy volunteers. Production of cGMP grade material of VB-601 for the Phase 1 trial was completed using a third party vendor, and the procedures required for study launch are being finalized. Initiation of this trial is subject to the progress and outcome of our corporate strategic process, and we may look to monetize this asset rather than continue development internally.

Prior to July 2022, our lead candidate was ofra-vec (VB-111), a custom designed therapeutic candidate comprised of a viral vector, promoter, and therapeutic gene. In July 2022, we announced top-line results from the Phase 3 OVAL clinical trial. The trial did not meet the primary endpoints of achieving a statistically significant improvement in progression-free survival (PFS), or overall survival (OS) and we discontinued the trial. We have conducted a strategic review of the ofra-vec program and have ceased further development of ofra-vec in all indications.

In August 2022, we announced a process to explore strategic alternatives to enhance shareholder value and engaged Chardan Capital Markets, LLC, or Chardan, as our exclusive financial advisor to assist in this process. Potential strategic options to be explored or evaluated as part of the process included, but were not limited to merger, reverse merger, other business combination, sale of assets, licensing, or other strategic transactions.

In August 2022, we also announced an organizational streamlining designed to reduce operating expenses and preserve capital as we explored strategic options to maximize shareholder value. As a result, and to date, have we reduced our workforce by approximately 84% of our full-time employees. As part of the organizational streamlining, Dr. Ron Cohen, Dr. Bennett Shapiro and Ms. Alison Finger resigned from our board of directors, effective August 1, 2022, reducing the number of members of our board of directors from nine to six.

Recent Developments

Proposed Merger with Notable Labs, Inc.

On February 22, 2023, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Notable and Vibrant Merger Sub, Inc., a Delaware corporation and our direct, wholly-owned subsidiary, or Merger Sub, pursuant to which, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Notable will be merged with and into Merger Sub (which transaction we refer to throughout this Annual Report on Form 10-K as the Merger) at the effective time of the Merger, or the Effective Time, with Notable continuing after the Merger as the surviving corporation and our wholly-owned subsidiary. The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

At the Effective Time, each outstanding share of Notable capital stock will be converted into the right to receive our ordinary shares, as set forth in the Merger Agreement. Under the exchange ratio formula in the Merger Agreement, immediately following the Effective Time, the former Notable securityholders are expected to own approximately 76% of our ordinary shares on a fully diluted basis and subject to adjustment and our securityholders of VBL as of immediately prior to the Effective Time are expected to own approximately 24% of our ordinary shares on a fully diluted basis and subject to adjustment. Under certain circumstances further described in the Merger Agreement, the ownership percentages may be adjusted upward or downward based on the level of our net cash at the closing of the Merger, and the terms and net proceeds of Notable's pre-merger financing. There can be no assurances as to our level of net cash between the signing of the Merger Agreement and the closing of the Merger.

The Merger Agreement contains a customary "no-shop" provision under which neither we nor Notable is permitted to (i) solicit any alternative acquisition proposals, (ii) furnish any non-public information to any person in connection with or in response to any alternative acquisition proposal, (iii) engage in any negotiations or discussions with any person with respect to any alternative acquisition proposal, (iv) approve, endorse or recommend any alternative acquisition proposal, or (v) execute or enter into any agreement relating to any alternative acquisition proposal. The "no-shop" provision is subject to certain exceptions that permit the board of directors of either party to comply with its fiduciary duties, which, under certain circumstances, would enable us or Notable to provide information to, and enter into discussions or negotiations with, third parties in response to any alternative acquisition proposals.

The Merger Agreement contains customary representations, warranties and covenants made by Notable and our company, including representations relating to obtaining the requisite approvals of the securityholders of Notable and our company, agreements relating to indemnification of directors and officers, and covenants relating to Notable's and our conduct our respective businesses between the date of signing the Merger Agreement and the Effective Time.

The Merger Agreement provides each of our company and Notable with specified termination rights, and further provides that, upon termination of the Merger Agreement under specified circumstances, the terminating party may be required to pay the other party a termination fee of $2,500,000. In addition, in connection with certain terminations of the Merger Agreement, we may be required to pay Notable's out-of-pocket fees and expenses up to $500,000, or Notable may be required to pay our out-of-pocket fees and expenses up to $500,000.

The Merger Agreement provides that, immediately following the Effective Time, the board of directors of the combined company will consist of up to seven directors, with one director designated by us. Upon the closing of the transaction, the combined company will be led by Notable's chief executive officer and executive management team. In connection with the Merger, we will seek to amend our articles of incorporation to: (i) effect an increase of our registered share capital and/or effect a reverse split of our ordinary shares at a ratio to be determined; (ii) change our name to "Notable Labs, Ltd."; and (iii) make other such changes as mutually agreeable to our company and Notable.

Our and Notable's obligations to consummate the Merger are subject to the satisfaction or waiver of customary closing conditions, including, among others, obtaining the requisite approval of our shareholders, obtaining the requisite approval of Notable's stockholders, proceeds of Notable's pre-closing financing, net of certain specified expenses, not being less than $5,000,000 and our net cash not being less than $15,000,000.

In connection with the execution of the Merger Agreement, we and Notable entered into shareholder support agreements with our current directors and executive officers who collectively beneficially own or control an aggregate of approximately 2% of our outstanding ordinary shares. These shareholder support agreements provide that, among other things, each of the shareholders has agreed to vote or cause to be voted all of its ordinary shares beneficially owned by such shareholder in favor of the issuance of our ordinary shares in the Merger at the VBL shareholder meeting to be held in connection with the Merger.

Although we have entered into the Merger Agreement and intend to consummate the proposed Merger, there is no assurance that we will be able to successfully consummate the proposed Merger on a timely basis, or at all. If, for any reason, the proposed Merger is not completed, we will reconsider our strategic alternatives and could pursue one or more of the following courses of action:

- Pursue potential collaborative, partnering or other strategic arrangements for our assets, including a sale or other divestiture of our assets, such as VB-601; or in-licensing additional programs and assets to develop internally.
- Pursue another strategic transaction like the proposed Merger. Our board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the proposed Merger.
- Dissolve and liquidate our assets. If, for any reason, the proposed Merger is not consummated and we are unable to identify and complete an alternative strategic transaction like the Merger or potential collaborative, partnering or other strategic arrangements for our assets, or to continue to operate our business due to our inability to raise additional funding, we may be required to dissolve and liquidate our assets. In such case, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to our shareholders after paying our debts and other obligations and setting aside funds for reserves.

Sale of Assets in the Modi'in Facility

On February 15, 2023, we entered into an Asset Purchase Agreement, or the Purchase Agreement, providing for the sale of our rights to lease the Modi'in manufacturing facility, along with certain tangible assets and equipment located therein for $7.1 million. We intend to use the proceeds from the asset sale to meet the $15.0 million minimum net cash closing condition provided in the Merger Agreement and are disposing of such rights in contemplation of the Merger (although completion of such asset sale is not a condition to the Merger). There can be no guarantee that we will have sufficient funds to satisfy the minimum net cash closing required pursuant to the Merger Agreement. We completed the asset sale on March 9, 2023. We have retained the right to use a portion of the space for a nominal fee until May 31, 2023.

Platform Technology

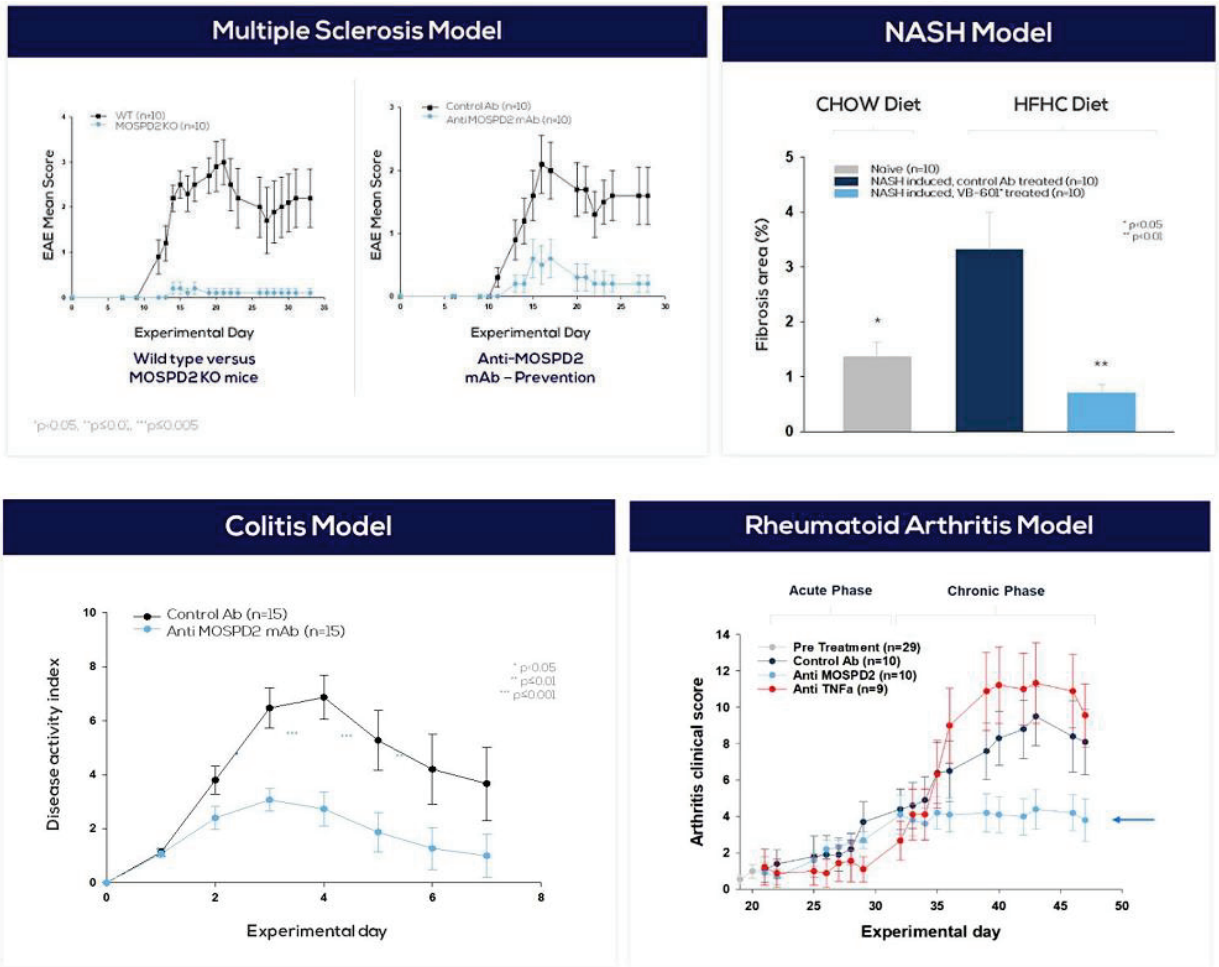
Monocyte Targeting Technology

Our monocyte targeting technology, or MTT, is based on the internal discovery of a novel target, MOSPD2. This novel target, which we call the "mono-walk" receptor, is selectively expressed on the surface of monocytes and controls their ability to migrate (or "walk" to) inflamed tissues. Monocytes are an important cell implicated in the chronicity of disease in inflammatory indications and previous attempts by others to specifically target this cell type and prevent its migration to sites of inflammation have been unsuccessful. We believe that our approach can address this gap in being able to optimally address chronic inflammation and we are utilizing antibody technology to specifically inhibit this target with high potency.

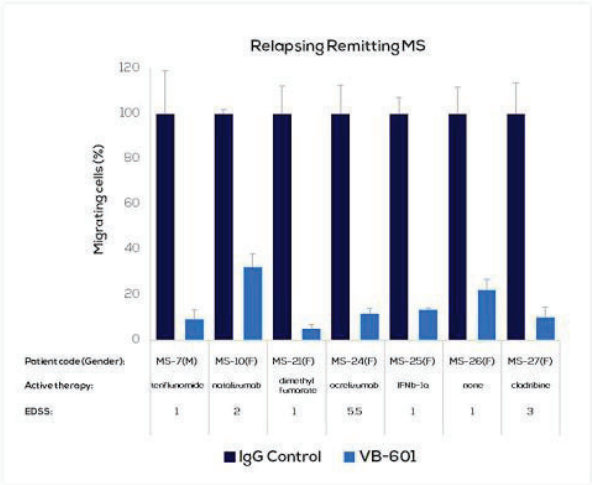
VB-601 Program- MTT Candidate

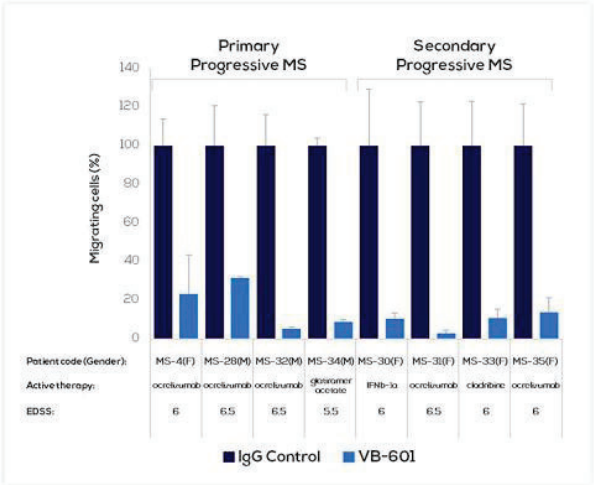
Our current MTT candidate, VB-601, is an investigational proprietary monoclonal antibody that binds the MOSPD2 surface protein, which we call the "mono-walk" receptor, and is engineered to specifically prevent monocytes from exiting the blood stream and traveling to inflamed tissues. Monocytes are one of the key cells types in inflammation and particularly implicated in being responsible for the chronicity of disease. VB-601 is designed to offer a novel and differentiated approach in the landscape of current anti-inflammatory agents, most of which target pro-inflammatory molecules and work through T and B lymphocytes but are not targeted to the monocyte cells.

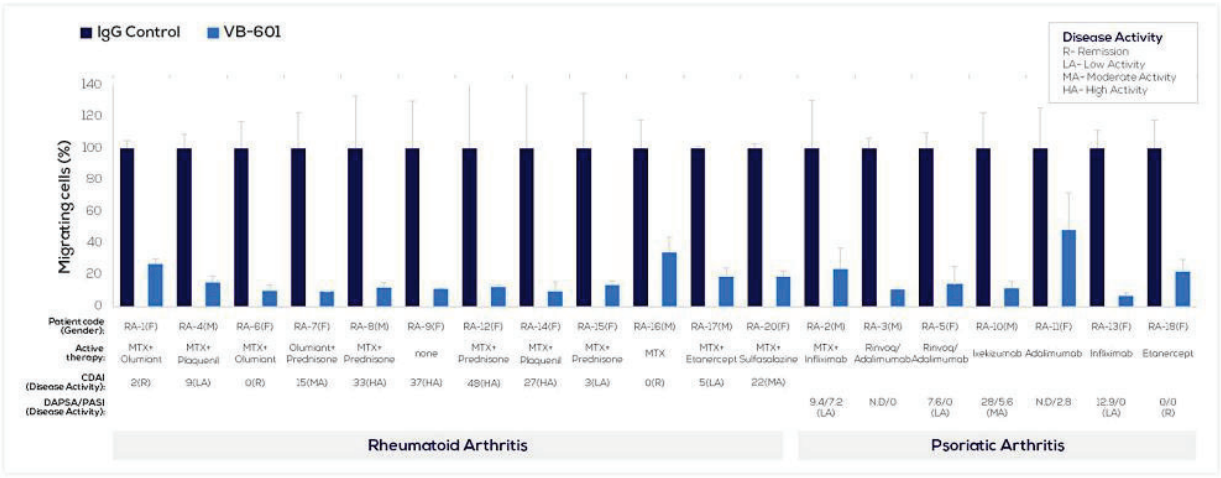
We have conducted various *in-vivo* pharmacology studies that demonstrate VB-601's potential activity against a broad range of prevalent chronic inflammatory indications:

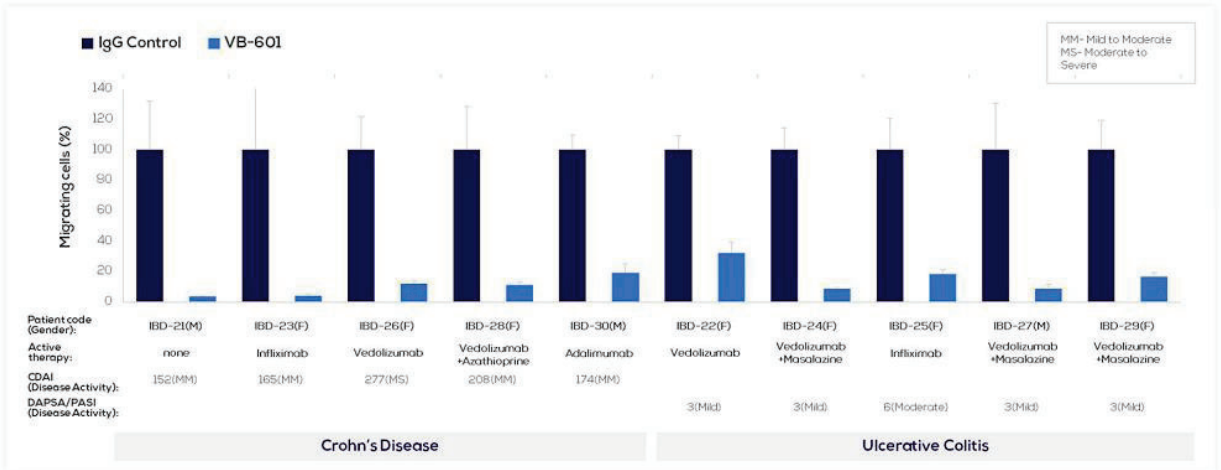


We have also performed *ex-vivo* proof-of-concept studies demonstrating the ability of VB-601 to inhibit migration of monocytes isolated from blood samples of patients with a broad range of prevalent chronic inflammatory indications:









Based on our preclinical *in-vivo* and human *ex-vivo* data, we believe VB-601 has potential utility in a wide range of immune-inflammatory diseases, such as multiple sclerosis (relapsing-remitting (RRMS) and progressive (PMS)), rheumatoid arthritis (RA), psoriatic arthritis (PsA), non-alcoholic steatohepatitis (NASH), inflammatory bowel disease (including Crohn's disease (CD) and ulcerative colitis (UC)) and other immune-inflammatory diseases.

We had a successful pre-IND meeting with the FDA regarding our development plan and have since completed IND-enabling toxicology studies that demonstrated a favorable tolerability profile that supports moving VB-601 into the clinic. Additionally, in October 2022, we submitted an application to the Israel Ministry of Health and institutional review board for a first-in-human Phase 1 trial evaluating VB-601 in healthy volunteers. We used a third-party vendor for cGMP grade material of VB-601 for the Phase 1 clinical trial and are currently finalizing the procedures required to initiate this Phase 1 clinical trial. Initiation of this clinical trial is subject to the progress and outcome of the proposed Merger and we continue to explore strategic transactions to monetize this asset, which could result in ceasing internal development altogether.

Our Strategy

In August 2022, we announced a process to explore strategic alternatives to enhance shareholder value and engaged Chardan as our exclusive financial advisor to assist in this process. Potential strategic options explored or evaluated as part of the process included, but were not limited to merger, reverse merger, other business combination, sale of assets, licensing, or other strategic transactions. As a result of this process, we entered into the Merger Agreement and recently closed the sale of our lease and certain related assets in our Modi'in facility.

While our current focus is on completing the Merger to maximize value for our shareholders, we will also continue to explore options for our product candidate, VB-601. We do not anticipate further development of this asset if the Merger is completed given the shift in strategic focus if the Merger is successful. However, there is no guarantee that we will be successful in identifying any strategic transaction for VB-601 or that we will be able to monetize or further develop this asset.

Competition

Inflammation is a defensive reaction involving the immune system. However, chronic inflammation can cause tissue damage and remodeling, which may cause the body's immune system to attack its own organs. There are various chronic inflammatory diseases, including multiple sclerosis, rheumatoid arthritis, lupus, ulcerative colitis, Crohn's disease, among others. Many of these diseases are insufficiently managed by existing treatments that provide mostly symptomatic relief. Certain therapies that target T or B lymphocytes can offer new possibilities for some of the patients, yet there is still an huge unmet need.

Unlike existing therapies, VB-601 is designed to target monocytes, a key component in chronic inflammation that is currently lacking therapeutic options. We believe VB-601 offers differentiated technology, based on VBL's newly discovered biology - blocking the ability of monocytes to reach inflamed tissues via MOSPD2. While there are numerous drug candidates in development for inflammatory indications, to the best of our knowledge, no other drug candidate are designed to target MOSPD2.

Governmental Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics. We, along with our vendors, contract research organizations, or CROs, clinical investigators and contract development and manufacturing organizations, or CDMOs, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and biologics and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and biologics under the FD&C Act and the Public Health Service Act, or PHSA, as amended, and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other regulatory requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, suspension or revocation of approved applications, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

Our product candidate must be approved for therapeutic indications by the FDA before it may be marketed in the United States. For biologic product candidates regulated under the FD&C Act and PHSA, FDA must approve a BLA. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- completion of the manufacture, under current good manufacturing practice, or cGMP requirements, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin and must be updated annually and when certain changes are made;
- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- preparation and submission to the FDA of a BLA;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of one or more FDA pre-license inspections of the manufacturing facility or facilities where the product will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- satisfactory completion of FDA audit of the clinical trial sites that generated the data in support of the BLA;
- payment of user fees for FDA review of the BLA, unless a waiver applies; and
- FDA review and approval of the BLA, including, where applicable, consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the product in the United States.

Preclinical Studies and Clinical Trials for Biologics

Before testing any biologic in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of product chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulation and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND.

An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes the results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls, or CMC, information; and any available human data or literature to support the use of the investigational product. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a full or partial clinical hold. FDA must notify the sponsor of the grounds for the hold and any identified deficiencies must be resolved before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A clinical hold can also be imposed once a trial has already begun, thereby halting the trial until the deficiencies articulated by FDA are corrected.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, who generally are physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements 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 clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable compared to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the 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 data and safety monitoring committee, or DSMC. This group provides authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than Phase 1 investigations, must be submitted within specific timeframes for publication on www.ClinicalTrials.gov, a clinical trials database maintained by the National Institutes of Health.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, FDA will nevertheless accept the results of the study in support of an NDA if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support a BLA for marketing approval are typically conducted in three sequential phases, which may overlap.

- *Phase 1*—Phase 1 clinical trials involve initial introduction of the investigational product in a limited population of healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism, distribution and excretion of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- *Phase 2*—Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the product's potential efficacy, to determine the optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.

- *Phase 3*—Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling. Generally, two adequate and well-controlled Phase 3 trials are required by the FDA for approval of a BLA.

Post-approval trials, sometimes referred to as Phase 4 clinical trials or post-marketing studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of a BLA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Marketing Approval for Biologics

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's CMC and proposed labeling, among other things, are submitted to the FDA as part of a BLA. A BLA is a request for approval to market a new biologic for one or more specified indications and must contain proof of the biologic's safety, purity and potency for the requested indications. The marketing application is required to include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings, together with detailed information relating to the product's CMC, and proposed labeling, among other things. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the investigational biologic, to the satisfaction of the FDA. The FDA must approve a BLA before a biologic may be marketed in the United States.

The FDA reviews all submitted BLAs to ensure they are sufficiently complete to permit substantive review before it accepts them for filing and may request additional information rather than accepting the BLA for filing. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews a BLA to determine, among other things, whether the product is safe and effective for the indications sought and whether the facility in which it is manufactured, processed, packaged or held meets standards designed, including cGMP requirements, designed to assure and preserve the product's continued identity, strength, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity BLA and respond to the applicant, and six months from the filing date of a new molecular entity BLA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, if it believes that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the biologic outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, special monitoring or other risk-minimization tools.

The FDA may refer an application for a novel biologic to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the complete response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the complete response letter, the FDA may require additional clinical or preclinical testing or recommend other actions, such as requests for additional information or clarification, that the applicant might take in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a biologic intended to treat a rare disease or condition, which is a disease or condition with either a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States when there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs for Biologics

The FDA maintains several programs intended to facilitate and expedite development and review of new biologics to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include fast track designation, breakthrough therapy designation, priority review and accelerated approval, and the purpose of these programs is to either expedite the development or review of important new biologics to get them to patients more quickly than standard FDA review timelines typically permit.

A new biologic is eligible for fast track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. Fast track designation provides increased opportunities for sponsor interactions with the FDA during clinical development, in addition to the potential for rolling review once a marketing application is submitted. Rolling review means that the FDA may review portions of the marketing application before the sponsor submits the complete application.

In addition, a new biologic may be eligible for breakthrough therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the biologic, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation provides all the features of fast track designation in addition to intensive guidance on an efficient product development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with fast track or breakthrough therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including priority review designation and accelerated approval. A biologic is eligible for priority review, once a BLA is submitted, if the product that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review. Products may be eligible for accelerated approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Accelerated approval is usually contingent on a sponsor's agreement to conduct, in a diligent manner, adequate and well-controlled additional post-approval confirmatory studies to verify and describe the product's clinical benefit and, under the Food and Drug Omnibus Reform Act, or FDORA, the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after accelerated approval is granted. Additionally, under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a product or an indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the Agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act, or PREA, as amended, certain BLAs and certain BLA supplements must contain data that can be used to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The FD&C Act requires that a sponsor who is planning to submit a marketing application for a product candidate that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Unless otherwise required by regulation, PREA does not apply to a biologic for an indication for which orphan drug designation has been granted.

A drug or biologic can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

U.S. Post-Approval Requirements for Biologics

Biologics manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe approved products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, including not only by company employees but also by agents of the company or those speaking on the company's behalf, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties, including liabilities under the False Claims Act where products are obtain reimbursement under federal health care programs. Promotional materials for approved biologics must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of a BLA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, manufacturers and their subcontractors involved in the manufacture and distribution of approved biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements on sponsors and their CMOs. 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 requirements upon us and any third party manufacturers that a sponsor may use. Manufacturers and manufacturers' facilities are also required to comply with applicable product tracking and tracing requirements. 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. Failure to comply with statutory and regulatory requirements may subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual program user fee for any marketed product.

The FDA may withdraw approval of a product 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, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or
- mandated modification of promotional materials and labeling and issuance of corrective information.

United States Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of our product candidate, one of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved product, a method for using it or a method for manufacturing it may be extended. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of aa BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved biologic is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, or U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond a patent's current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2012, collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach for the review and approval of biosimilars in the United States. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. The FDA may approve multiple "first" interchangeable products so long as they are all approved on the same first day of marketing. This exclusivity period, which may be shared amongst multiple first interchangeable products, lasts until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). Products deemed "interchangeable" by the FDA may be readily substituted by pharmacies, and such substitution is governed by state pharmacy law.

Other Regulatory Matters

Following product approval, where applicable, the manufacturing, sales, promotion and other activities around product candidates and/or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA. Regulatory agencies with authority over product candidates may include, and are not limited to, the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

If any products that we may develop are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, labeling, packaging, distribution, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to which we may be subject.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive recordkeeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements may subject firms to legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling or packaging; (iii) the recall or discontinuation of our products; or (iv) additional recordkeeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other Healthcare Laws

If we obtain regulatory approval of our products, we may be subject to various federal and state laws targeting fraud, waste, 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 U.S. laws that may affect our ability to operate include:

- the U.S. 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 in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. In addition, 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 federal civil False Claims Act or federal civil money penalties statute (as discussed below);

- U.S. federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent, making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA and its implementing regulations, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and prohibit 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose certain obligations, including mandatory contractual terms, on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the U.S. federal Physician Payments Sunshine Act which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments or transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and laws and regulations in other jurisdictions, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers, and state and laws in other jurisdiction governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payers, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, in the event we obtain regulatory approval for any one of our products, it is possible that some of our business activities could be subject to challenge and found to violate one or more of such laws, regulations, and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Violations of these laws can subject us to administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs.

Insurance Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. In the United States, sales of any products for which we may 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 programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. The process for determining whether a payer will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payer will pay for the drug product. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payers tend to follow CMS to a substantial degree. Third-party payers may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a payer's decision to provide coverage for a drug 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. In order to obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Factors payers consider in determining reimbursement are based on whether the 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.

Our 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 a company to sell its products at a profit.

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs reimbursed by 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. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on cost containment measures in the United States has increased and 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.

Current and Future Healthcare Reform Legislation

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements.

In March 2010, the ACA was enacted, which includes measures that have or will significantly change the way health care is financed by both U.S. governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of average manufacturer price, or AMP, and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by expanding the population potentially eligible for Medicaid drug benefits. In addition, the ACA provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program.
- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. The ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.
- Expansion of the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability.
- The ACA imposed a requirement on manufacturers of branded drugs to provide a 70% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (increased from 50% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019).
- The ACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.
- A Patient-Centered Outcomes Research Institute was established pursuant to the ACA to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.
- The ACA established the Center for Medicare and Medicaid Innovation within CMS, which is charged with testing new, innovative payment and service delivery models.

Since its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the temporary suspension, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022.

- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug or biological products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021 CMS rescinded the Most Favored Nations rule. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

Other U.S. Environmental, Health and Safety Laws and Regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses that we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Government Regulation of Biologics Outside of the United States

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. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union and in other jurisdictions, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

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, on January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 became directly applicable in all the European Union Member States and simplifies and streamlines the approval of clinical trials in the European Union. The transitory provisions of the new Regulation provide that ongoing clinical trials authorized under the previous EU Clinical Trials Directive can remain under the Directive, or they can transition to the Regulation. By January 31, 2025, all ongoing clinical trials must have transitioned to the new Regulation. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "Clinical Trials Information System", a single set of documents to be prepared and submitted for the application; and a harmonized procedure for the assessment of applications for clinical trials. Strict deadlines have also been established for the assessment of clinical trial applications. To obtain regulatory approval of a medicinal product under European Union regulatory systems, we must submit a marketing authorization application. The application required in the European Union is similar to a BLA in the United States, with the exception of, among other things, country-specific document requirements. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union, for a period of eight years from the date on which the reference product was first authorized in the European Union. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. The innovator may obtain an additional one year of market exclusivity if the innovator obtains an additional authorization during the initial eight year period for one or more new indications that demonstrate significant clinical benefit over existing therapies. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. The same exclusivity periods are available for new biologics.

Orphan medicinal products in the European Union are eligible for 10-year market exclusivity. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. This 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. During the period of market exclusivity, a marketing authorization may only be granted to a "similar medicinal product" for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the authorized product;
- the marketing authorization holder for the authorized orphan product consents to a second orphan medicinal product application; or
- the marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product.

The European Union adopted the new Clinical Trials Regulation (EU) No 536/2014 in April 2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022. The transitory provisions of the new Regulation offer sponsors the possibility to choose between the requirements of the previous Directive and the new Regulation if the request for authorization of a clinical trial is submitted in the year after the new Regulation became applicable. If the sponsor chooses to submit under the Directive, the clinical trial continues to be governed by the previous Directive until three years after the new Regulation became applicable. If a clinical trial continues for more than three years after the Regulation became applicable, the new Regulation will at that time begin to apply to the clinical trial. The new Regulation overhauls the system of approvals for clinical trials in the European Union. Specifically, it is directly applicable in all Member States (meaning that no national implementing legislation in each Member State is required), and aims at simplifying and streamlining the approval of clinical trials in the European Union. The main characteristics of the new Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all European Union Member States in which an application for authorization of a clinical trial has been submitted (Concerned Member States) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Concerned Member State. Strict deadlines have also been established for the assessment of clinical trial applications.

The requirements and process governing the conduct of clinical trials, product approval or licensing, pricing and reimbursement 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 a medicinal product under European Union regulatory systems, we must submit a marketing authorization application. The application required in the European Union is similar to a BLA in the United States, with the exception of, among other things, country-specific document requirements. Marketing approvals in multiple European Union Member States may be obtained through a centralized, mutual recognition or decentralized procedure. The centralized procedure results in the grant of a single marketing authorization that is valid throughout the European Union Member States, as well as the additional Member States of the European Economic Area (Norway, Iceland and Liechtenstein).

Pursuant to Regulation (EC) No. 726/2004, as amended, the centralized procedure is mandatory for certain products, including those developed by means of specified biotechnological processes, advanced therapy medicinal products (gene-therapy, somatic-cell therapy, and tissue-engineered products), products for human use containing a new active substance for which the therapeutic indication is the treatment of specified diseases, including AIDS, HIV, cancer, diabetes, neurodegenerative disorders, auto-immune diseases and other immune dysfunctions and viral diseases, as well as products designated as orphan medicinal products. The Committee for Medicinal Products for Human Use, or CHMP, of the EMA also has the discretion to permit other products to use the centralized procedure if it considers them sufficiently innovative or they contain a new active substance or they may be of benefit to public health at the European Union level.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application by the EMA 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 CHMP. Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days, excluding clock stops, but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Now that the UK (which comprises Great Britain and Northern Ireland) has left the European Union, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Ireland Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January 1, 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency the United Kingdom's medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents applicants for authorization of generics or biosimilars of these innovative products in the European Union from referencing the innovator's preclinical and clinical trial data when applying for a generic or biosimilar marketing authorization in the European Union, during a period of eight years from the date on which the reference product was first authorized in the European Union. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. The innovator may obtain an additional one year of market exclusivity if the innovator obtains an additional authorization during the initial eight year period for one or more new indications that demonstrate significant clinical benefit over currently approved therapies. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on a marketing authorization application with a completely independent data package of pharmaceutical tests, preclinical tests and clinical trials. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Similar exclusivity periods are available for new biologics.

A product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish: that (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) it is unlikely that the product, without the benefits derived from orphan status, would generate sufficient return in the European Union to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union or, if such method exists, the product will be of significant benefit to those affected by that condition. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The aforementioned European Union rules are generally applicable in the European Economic Area, which consists of the European Union Member States, plus Norway, Liechtenstein and Iceland.

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit, and the UK formally left the European Union on January 31, 2020. There was a transition period during which European Union pharmaceutical laws continued to apply to the United Kingdom, which expired on December 31, 2020. However, the European Union and the United Kingdom have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of United Kingdom and European Union pharmaceutical regulations. At present, Great Britain has implemented European Union legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the European Union regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore broadly aligns with current European Union regulations, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the European Union and the TCA does not provide for mutual recognition of United Kingdom and European Union pharmaceutical legislation.

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.

Intellectual Property

Our success depends, at least in part, on our ability to protect our proprietary technology and intellectual property, and to operate without infringing or violating the proprietary rights of others. We rely on a combination of patent, trademark, trade secret and copyright laws, know-how, intellectual property licenses and other contractual rights, including confidentiality and invention assignment agreements to protect our intellectual property rights.

See "Item 1A. Risk Factors—Risks Related to Our Intellectual Property" for additional discussion on our intellectual property and associated risks.

Patents

As of February 28, 2023, we have more than 148 granted patents and 28 applications pending worldwide for our former oncology program and VTS platform technology. We also have 33 granted patents and 22 applications pending worldwide for our VB-601 program and the MTT.

Trademarks

We rely on trade names, trademarks and service marks to protect our name brands. Our trademarks and registered trademarks in several countries include the following: "VTS," "VBL THERAPEUTICS," "VASCULAR TARGETING SYSTEM VTS," "VBL," "V VBL THERAPEUTICS & Design," "VASCULAR BIOGENICS," "V & Design," "GLOBE & Design," "OVAL & Design" "VENHIBO," "VENHEBO," and "  ("VBL Logo")".

Trade Secrets and Confidential Information

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We rely on, among other things, confidentiality and invention assignment agreements to protect our proprietary know-how and other intellectual property that may not be patentable, or that we believe is best protected by means that do not require public disclosure. For example, we require our employees to execute confidentiality agreements in connection with their employment relationships with us, and to disclose and assign to us inventions conceived in connection with their services to us. However, there can be no assurance that these agreements will be enforceable or that they will provide us with adequate protection.

We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business.

Sales and Marketing

We have not yet established sales, marketing or product distribution operations because our product candidate, VB-601, is an early-stage asset.

Manufacturing

We rely on third-party manufacturers to manufacture supplies for our product candidate, VB-601. We also contract with additional third parties for the formulating, labeling, packaging, storage and distribution of the final drug product.

In October 2017, we announced the opening of a 20,000 sq. ft. new gene therapy manufacturing plant in Modi'in, Israel, which was planned to be the commercial facility for production of our former lead product candidate, ofra-vec. Following the discontinuation of the OVAL trial and ofra-vec program in all indications, we sought to monetize this facility and in February 2023 entered into an agreement providing for the sale of our rights in this facility for $7.1 million, which transaction closed in March 2023. See "—Recent Developments— Sale of Assets in the Modi'in Facility" above.

Human Capital Resources

As of March 1, 2023, we had seven employees, mostly within general and administrative positions, to support our corporate strategic process and research and development. All of our employees are located in Israel with the exception of one employee in the United States, and three of our employees have either M.D.s or Ph.D.s. None of our employees currently work under any collective bargaining agreements. We have experienced significant employee turnover due to the reduction in force after the results of the OVAL study and termination of the ofra-vec program and sale of our rights in the Modi'in facility and pursuit of the proposed Merger and exploration of alternatives to monetize VB-601. This additional uncertainty has resulted in further employee resignations. We believe our employee relations with the remaining employees are good and we have provided additional severance considerations to retain such employees. See "Item 11. Executive Compensation" for additional information regarding these additional retention benefits.

Israeli labor laws govern the length of the workday, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination of employment, equal opportunity and anti- discrimination laws and other conditions of employment. Subject to specified exceptions, Israeli law generally requires severance pay upon the retirement, death or dismissal of an employee, and requires us and our employees to make payments to the National Insurance Institute, which is similar to the U.S. Social Security Administration. Our employees have defined benefit pension plans that comply with the applicable Israeli legal requirements.

Corporate Information

The legal name of our company is Vascular Biogenics Ltd., and we conduct business under the name VBL Therapeutics. We were incorporated in Israel on January 31, 2000 as a company limited by shares under the name Medicard Ltd. In February 2002, we changed our name to Vascular Biogenics Ltd. Our registered and principal office is located 8 HaSatat St., Modi'in, Israel 7178106 and our telephone number is 972-8-9935000. We also have a wholly owned U.S. subsidiary, VBL Inc., with an office located at 1 Blue Hill Plaza, Suite 1509, Pearl River, NY 10965. Our internet website address is www.vblrx.com. The information contained on, or that can be accessed through, our website is not a part of this Annual Report on Form 10-K.

Item 1A. RISK FACTORS

In February 2023, we entered into a Merger Agreement with Notable, pursuant to which, subject to the approval of our shareholders and the satisfaction or waiver of the conditions set forth in the Merger Agreement, if completed as proposed (which could be as early as the second quarter of 2023), Notable's stockholders would own a majority of the post-transaction entity, its management team would replace our management team, Notable's business would become our business, and its financial statements would become our financial statements under appliable accounting rules (e.g., Notable would be the "accounting acquiror" even though we would be the legal acquiror). Additional information regarding the proposed Merger including risk factors related to Notable will be found in VBL's registration statement on Form S-4 when filed with the U.S. Securities and Exchange Commission. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report, including the financial statements and the related notes included elsewhere in this Annual Report and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected.

Risks Related to the Proposed Merger

There is no assurance that the proposed Merger will be completed in a timely manner or at all. If the proposed Merger is not consummated, our business could suffer materially and our stock price could decline.

The closing of the proposed Merger is subject to the satisfaction or waiver of a number of closing conditions, as described above, including the required approvals by our shareholders and Notable's stockholders and other customary closing conditions. See "*—The proposed Merger is subject to approval of the Merger Agreement by our shareholders and the Notable stockholders. Failure to obtain these approvals would prevent the closing of the Merger*" and "*—If the conditions to the Merger are not met, the Merger will not occur*" below. If the conditions are not satisfied or waived, the proposed Merger may be materially delayed or abandoned. If the proposed Merger is not consummated, our ongoing business may be adversely affected and, without realizing any of the benefits of having consummated the proposed Merger, we will be subject to a number of risks, including the following:

- we have incurred and expect to continue to incur significant expenses related to the proposed Merger even if the Merger is not consummated;
- we could be obligated to pay Notable a termination fee equal to $2,500,000 and/or cover Notable's reasonable out-of-pocket expenses up to $500,000 under certain circumstances set forth in the Merger Agreement;
- the market price of our ordinary shares may decline to the extent that the current market price reflects a market assumption that the proposed Merger will be completed;
- we may not be able to meet the Nasdaq continued listing standards, which may lead to delisting procedures by Nasdaq; and
- matters relating to the proposed Merger have required and will continue to require substantial commitments of time and resources by our remaining management and employees, which could otherwise have been devoted to other opportunities that may have been beneficial to us.

We also could be subject to litigation related to any failure to consummate the proposed Merger or to perform our obligations under the Merger Agreement. If the proposed Merger is not consummated, these risks may materialize and may adversely affect our business, financial condition and the market price of our ordinary shares.

If the proposed Merger is not completed, we may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the proposed Merger with Notable, or at all, and we may otherwise be unable to continue to operate our business. Our board of directors may decide to pursue a dissolution and liquidation of VBL. In such an event, the amount of cash available for distribution to our shareholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

While we have entered into the Merger Agreement with Notable, the closing of the proposed Merger may be delayed or may not occur at all and there can be no assurance that the proposed Merger will deliver the anticipated benefits we expect or enhance shareholder value. If we are unable to consummate the proposed Merger, our board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the proposed Merger. Attempting to complete an alternative transaction like the proposed Merger will be costly and time consuming, and we can make no assurances that such an alternative transaction would occur at all. Alternatively, our board of directors may elect to continue our operations to advance the preclinical and clinical development of our program, which would require that we obtain additional funding, and to resume our efforts to seek potential collaborative, partnering or other strategic arrangements for our program, including a sale or other divestiture of our program assets, or our board of directors could instead decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our shareholders will depend heavily on the timing of such decision, and subject to the provisions of the Israeli Companies Law 5759-1999, or the Companies Law, and with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our shareholders were to approve, a voluntary liquidation of our company, our board of directors would be required under Israeli corporate law to declare that following examination of the company's state of affairs, the company will be able to pay its outstanding debts within twelve months from the date on which the voluntary liquidation commences, prior to making any distributions in liquidation to our shareholders. Our commitments and contingent liabilities may include severance obligations, regulatory and preclinical obligations, and fees and expenses related to the proposed Merger. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our ordinary shares could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of the company.

The issuance of our ordinary shares to Notable stockholders in the proposed Merger will substantially dilute the voting power of our current shareholders.

If the proposed Merger is completed, each outstanding share of Notable capital stock will be converted into the right to receive a number of our ordinary shares equal to the exchange ratio determined pursuant to the Merger Agreement. Immediately following the Merger, the former Notable equity holders immediately before the Merger are expected to own approximately 76.0% of our ordinary shares, and our equity holders immediately before the Merger are expected to own approximately 24.0% of our ordinary shares, each on a fully diluted basis as provided in the Merger Agreement and subject to certain assumptions. Accordingly, the issuance of our ordinary shares to Notable stockholders in the Merger will reduce significantly the relative voting power of each ordinary share held by our current shareholders. Consequently, our shareholders as a group will have significantly less influence over the management and policies of the combined company after the Merger than prior to the Merger. These estimates are based on the anticipated exchange ratio and are subject to adjustment as provided in the Merger Agreement. See also *"—The exchange ratio set forth in the Merger Agreement is not adjustable based on the market price of our ordinary shares, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed*" below.

The proposed Merger is subject to approval of the Merger Agreement by our shareholders and the Notable stockholders. Failure to obtain these approvals would prevent the closing of the Merger.

Before the proposed Merger can be completed, our shareholders and the stockholders of Notable must approve the Merger Agreement. Failure to obtain the required stockholder approvals may result in a material delay in, or the abandonment of, the Merger. Any delay in completing the proposed Merger may materially adversely affect the timing and benefits that are expected to be achieved from the proposed Merger.

The Merger may be completed even though certain events occur prior to the closing that materially and adversely affect our company or Notable.

The Merger Agreement provides that either we or Notable can refuse to complete the proposed Merger if there is a material adverse change affecting the other party between February 22, 2023, the date of the Merger Agreement, and the closing of the Merger that is continuing. However, certain types of changes do not permit either party to refuse to complete the proposed Merger, even if such change could be said to have a material adverse effect on our company or Notable, including:

- any effect resulting from the announcement or pendency of the proposed Merger or any related transactions;
- the taking of any action, or the failure to take any action, by either us or Notable required to comply with the terms of the Merger Agreement, and with respect to us, the taking of any action expressly permitted under Section 5.1(b) of the disclosure schedule appended to the Merger Agreement;
- any natural disaster or epidemics, pandemics or other force majeure events, or any act or threat of terrorism or war, any armed hostilities or terrorist activities (including any escalation or general worsening of any of the foregoing) anywhere in the world or any governmental or other response or reaction to any of the foregoing;
- any change in U.S. generally accepted accounting principles or any change in applicable laws, rules, or regulations or the compliance with or interpretation thereof;
- general economic or political conditions or conditions generally affecting the industries in which we or Notable, as applicable, operate;
- with respect to Notable, any change in the cash position of Notable that results from operations in the ordinary course of its normal operations and consistent with its past practices;
- with respect to our company, any change in our stock price or trading volume excluding any underlying effect that may have caused such change;
- with respect to our company, the suspension of trading in or delisting of our ordinary shares on Nasdaq; and
- with respect to our company, the sale or winding down of our business as conducted prior to the date of the Merger Agreement and our operations, and the sale, license or other disposition of all of our assets, technology and intellectual property as they existed at any time prior to the date of the Merger Agreement.

If adverse changes occur and we and Notable still complete the Merger, the market price of the combined organization's ordinary shares may suffer. This in turn may reduce the value of the Merger to the equityholders of our company, Notable or both.

Some of our and Notable's officers and directors have interests in the proposed Merger that are different from the respective securityholders, and that may influence them to support or approve the Merger without regard to the interests of the respective securityholders.

Certain officers and directors of our company and of Notable participate in arrangements that provide them with interests in the proposed Merger that are different from the interests of the respective securityholders, including, among others, the continued service as an officer or director of the combined organization, severance benefits, the acceleration of option vesting, continued indemnification and the potential ability to sell an increased number of ordinary shares of the combined organization in accordance with Rule 144 under the Securities Act of 1933, as amended.

For example, we have entered into certain employment and severance benefits agreements with certain of our executive officers that may result in the receipt by such executive officers of cash severance payments and other benefits in the event of a covered termination of employment of each executive officer's employment. The closing of the Merger will also result in the acceleration of vesting of options to purchase ordinary shares and restricted stock units, or RSUs, held by our executive officers and directors, whether or not there is a covered termination of such officer's employment. In addition, and for example, certain of Notable's directors and executive officers have options, subject to vesting, to purchase shares of Notable's capital stock that, at the closing of the Merger, will be converted into and become options to purchase our ordinary shares, certain of Notable's directors and executive officers are expected to become directors and executive officers of our company upon the closing of the Merger, and all of Notable's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. These interests, among others, may influence our officers and directors and those of Notable to support or approve the proposed Merger.

The market price of our ordinary shares following the Merger may decline as a result of the Merger.

The market price of our ordinary shares may decline as a result of the Merger for a number of reasons including if:

- investors react negatively to the prospects of the combined organization's product candidates, business and financial condition following the Merger;
- the effect of the Merger on the combined organization's business and prospects is not consistent with the expectations of financial or industry analysts; or

- the combined organization does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts.

Our equityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined organization following the closing of the Merger as compared to their current ownership and voting interest.

After the completion of the Merger, the current securityholders of our company and Notable will own a smaller percentage of the combined company than their ownership in their respective companies prior to the Merger. Immediately after the Merger, it is currently estimated that Notable equityholders will own approximately 76.0% of the ordinary shares of the combined company, and our equityholders, whose ordinary shares will remain outstanding after the Merger, will own approximately 24.0% of the Vibrant Ordinary Shares (as defined in the Merger Agreement) subject to certain assumptions. These estimates are based on the anticipated exchange ratio and are subject to adjustment as provided in the Merger Agreement. See also "*—The exchange ratio set forth in the Merger Agreement is not adjustable based on the market price of our ordinary shares, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed*" below.

In addition, the up to seven member board of directors of the combined company will initially include one individual with prior affiliations with our company. Consequently, our securityholders and those of Notable will be able to exercise less influence over the management and policies of the combined organization following the closing of the Merger than they currently exercise over the management and policies of their respective companies.

Our shareholders and Notable stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If the combined company is unable to realize the strategic and financial benefits currently anticipated from the proposed Merger, our shareholders and Notable's stockholders will have experienced substantial dilution of their ownership interests in their respective companies without receiving the expected commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the expected strategic and financial benefits currently anticipated from the proposed Merger.

The combined company will need to raise additional capital by issuing securities or debt or through licensing or other strategic arrangements, which may cause dilution to the combined company's shareholders or restrict the combined company's operations or impact its proprietary rights.

The combined company may be required to raise additional funds sooner than currently planned. In this regard, the exchange ratio may be impacted by cash levels of the respective companies at the closing of the Merger. The Merger Agreement conditions the completion of the Merger upon us holding a minimum amount of cash greater than or equal to $15,000,000 at the effective time of the Merger. The Merger Agreement does not condition the completion of the Merger upon Notable holding a minimum amount of cash at the effective time of the Merger. If either or both of our company or Notable hold less cash at the time of the closing Merger than the parties currently expect, the combined company will need to raise additional capital sooner than expected. Additional financing may not be available to the combined company when it needs it or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such an issuance may cause significant dilution to the combined company's shareholders' ownership and the terms of any new equity securities may have preferences over the combined company's ordinary shares. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing, partnering or other strategic arrangements, it may be necessary to relinquish rights to some of the combined company's technologies or product candidates and proprietary rights, or grant licenses on terms that are not favorable to the combined company.

During the pendency of the proposed Merger, we and Notable may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect our respective businesses.

Covenants in the Merger Agreement impede our ability and that of Notable to make acquisitions, subject to certain exceptions relating to fiduciary duties, as set forth below, or to complete other transactions that are not in the ordinary course of business pending completion of the proposed Merger. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during such period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, initiating, encouraging or entering into certain extraordinary transactions, such as a merger, sale of assets, or other business combination outside the ordinary course of business with any third party, subject to certain exceptions relating to fiduciary duties. Any such transactions could be favorable to such party's stockholders.

Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit each of us and Notable from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when such party's board of directors determines in good faith that an unsolicited bona fide alternative takeover proposal is more favorable, from a financial point of view, to either our shareholders or Notable's stockholders, as applicable, than the terms of the Merger and is not subject to any financing conditions (or, if financing is required, such financing is then fully committed to the third party). With respect to us, our board of directors must also determine in good faith that the failure to enter into such alternative takeover proposal would reasonably be expected to be inconsistent with its fiduciary obligations, and we are required to pay a termination fee of $2,500,000.

The exchange ratio set forth in the Merger Agreement is not adjustable based on the market price of our ordinary shares, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.

The Merger Agreement has set the exchange ratio for the Notable capital stock, and the exchange ratio is based on the outstanding capital stock of Notable and our outstanding ordinary shares, in each case immediately prior to the closing of the Merger. Applying the exchange ratio formula in the Merger Agreement, the former Notable equityholders immediately before the Merger are expected to own approximately 76.0% of the combined company's outstanding ordinary shares immediately following the Merger, and our equityholders immediately before the Merger are expected to own approximately 24.0% of the combined company's outstanding ordinary shares, each on a fully diluted basis as provided in the Merger Agreement. Under certain circumstances further described in the Merger Agreement, however, these ownership percentages may be adjusted upward or downward based on cash levels of the respective companies at the closing of the Merger and the terms and net proceeds of Notable's pre-merger financing, and as a result, either our shareholders or the Notable stockholders could own less of the combined company than expected.

Any changes in the market price of our ordinary shares before the completion of the Merger will not affect the number of ordinary shares issuable to Notable's stockholders pursuant to the Merger Agreement. Therefore, if before the completion of the Merger the market price of our ordinary shares declines from the market price on the date of the Merger Agreement, then Notable's stockholders could receive merger consideration with substantially lower value than the value of such merger consideration on the date of the Merger Agreement. Similarly, if before the completion of the Merger the market price of our ordinary shares increases from the market price of our ordinary shares on the date of the Merger Agreement, then Notable's stockholders could receive merger consideration with substantially greater value than the value of such merger consideration on the date of the Merger Agreement. The Merger Agreement does not include a price-based termination right. Because the exchange ratio does not adjust as a result of changes in the market price of our ordinary shares, for each one percentage point change in the market price of our ordinary shares, there is a corresponding one percentage point rise or decline, respectively, in the value of the total merger consideration payable to Notable's stockholders pursuant to the Merger Agreement.

Because the lack of a public market for Notable's capital stock makes it difficult to evaluate the value of Notable's capital stock, the stockholders of Notable may receive our ordinary shares in the Merger that have a value that is less than, or greater than, the fair market value of Notable's capital stock.

The outstanding capital stock of Notable is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Notable. Because the percentage of our ordinary shares to be issued to Notable's stockholders was determined based on negotiations between the parties, it is possible that the value of our ordinary shares to be received by Notable's stockholders will be less than the fair market value of Notable, or we may pay more than the aggregate fair market value for Notable.

If the conditions to the Merger are not met, the Merger will not occur.

Even if the Merger is approved by our shareholders and Notable stockholders, specified conditions must be satisfied or waived to complete the Merger. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger will not occur or will be delayed, and we and Notable each may lose some or all of the intended benefits of the proposed Merger.

Litigation relating to the proposed Merger could require us or Notable to incur significant costs and suffer management distraction, and could delay or enjoin the proposed Merger.

We and Notable could be subject to demands or litigation related to the proposed Merger, whether or not the Merger is consummated. Such actions may create uncertainty relating to the Merger, or delay or enjoin the Merger. Litigation is often expensive and diverts management's attention and resources, which could adversely affect our or Notable's business.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We are an early clinical-stage biotechnology company, and we have not yet generated any regular revenue streams. We have incurred losses in each year since our inception in 2000, including net losses of $32.3 million and $29.9 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $294.4 million.

Historically, we have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. To date, we have financed our operations primarily through the sale of equity securities and convertible debt and, to a lesser extent, through grants from governmental agencies. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or additional grants. We have never completed a pivotal clinical trial for any of our product candidates. Ofra-vec, our former product candidate did not meet the primary endpoint in our Phase 3 OVAL trial and accordingly, we ceased development of ofra-vec in August 2002. Our current product candidate, VB-601, is in very early stages and it will be a few years, if ever, before we have a product candidate ready for commercialization. Even if we decided to pursue future clinical trials of VB-601 or any other product candidates and they are successful such that we obtain regulatory approval to market a product, our future revenues will depend upon the size of any markets in which such product receives approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payers and adequate market share for any approved product in those markets.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our research, preclinical, and clinical development activities for our product candidate and future product candidates;
- conduct current clinical trials for our product candidate;
- initiate additional research, preclinical, clinical or other studies for our product candidate;
- seek regulatory and marketing approvals for our product candidate if such candidate successfully completes clinical trials;
- further develop the manufacturing process for our product candidate using a third-party manufacturer;
- change or add additional manufacturers or suppliers;
- establish a sales, marketing and distribution infrastructure to commercialize any product for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license or other intellectual property related agreements from any licensing arrangements we may enter into the future;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company;
- transition from being a foreign private issuer to a U.S. reporting company; and
- experience any delays or encounter issues with any of the above.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our share price to decline.

We have never generated any revenue from product sales and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, obtain the regulatory approvals of, and commercialize a product candidate. We do not anticipate generating revenues from product sales for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing research, preclinical, and clinical development activities for a product candidate;
- successful outcomes from our current and future trials evaluating a product candidate;
- obtaining regulatory and marketing approvals for a product candidate for which we complete successful clinical trials;
- developing a sustainable, scalable, reproducible, and transferable manufacturing process for a product candidate;

- establishing and maintaining supply and manufacturing relationships with third parties that can provide products and services adequate, in amount and quality, to support clinical development and the market demand for a product candidate, if approved;
- launching and commercializing any product candidate for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining market acceptance of any product candidate that receives regulatory approval as a viable treatment options;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- identifying and validating new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other regulatory agencies, domestic or foreign, to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved product, we may not become profitable and may need to obtain additional funding to continue operations.

We are not in compliance with Nasdaq's minimum bid price requirement and if we fail to regain compliance with Nasdaq's continued listing requirements, our ordinary shares could be delisted, which could adversely affect the liquidity of our ordinary shares and our ability to raise additional capital or complete the Merger. The Merger is a "change of control" and the combined company will need to satisfy all of Nasdaq's initial listing criteria to remain listed on Nasdaq.

On August 31, 2022, we received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market LLC, or Nasdaq, notifying us that our listed securities did not maintain the minimum bid price requirement of $1.00 per ordinary share for continued listing on The Nasdaq Global Market for a period of 30 consecutive business days as required under Nasdaq Listing Rule 5450(a)(1). Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum closing bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days.

In accordance with Nasdaq's Listing Rule 5810(c)(3)(A), we had a period of 180 calendar days, or until February 27, 2023, or the Compliance Period, to regain compliance with the minimum closing bid price requirement. If at any time during the Compliance Period, our ordinary shares had a closing bid price of at least $1.00 for 10 consecutive business days, Nasdaq would have provided us a written confirmation of compliance and the matter would have been closed. However, we did not regain compliance by February 27, 2023, requested a transfer of our listing to the Nasdaq Capital Market, and received an additional 180 day period to regain compliance. If, compliance with the minimum closing bid price requirement cannot be demonstrated by the end of this second compliance period, Nasdaq will provide written notification that our ordinary shares will be delisted. At that time, we may appeal Nasdaq's determination to a Hearings Panel. We intend to monitor the closing bid price of our ordinary shares and may, if appropriate, consider available options to regain compliance with the minimum bid price requirement. If we complete the merger with Notable, this will be deemed a "change in control" under Nasdaq's rules, and the combined company will need to satisfy all of Nasdaq's initial listing criteria. If the merger is consummated and the combined entity fails to either qualify for listing or timely complete Nasdaq's initial listing process prior to consummation, this could also result in a suspension of trading and possible delisting.

We have undergone a significant workforce reduction to reduce operating expenses and extend our cash runway, but such efforts may not yield the anticipated benefits, which could have a material effect on our operations.

On August 2, 2022, we announced an organizational streamlining designed to reduce operating expenses and preserve capital. As a result, to date, we reduced have significantly reduced our workforce and currently have only seven full-time employees. As part of the organizational streamlining, Dr. Ron Cohen, Dr. Bennett Shapiro and Ms. Alison Finger resigned from our board of directors, effective August 1, 2022, reducing the number of members of our board of directors from nine to six. The reduction in workforce is expected to reduce operating expenses and extend our cash runway, but the reduction in workforce may not have as significant a benefit as anticipated. As a result, we may need to raise additional capital or take additional measures to be able to continue our operations as expected and consummate any strategic transaction, including the Merger or any transaction involving VB-601.

We are exploring strategic alternatives to enhance shareholder value, including the proposed Merger with Notable, transactions involving VB-601 and the recently completed sale of our Modi'in facility lease rights. We may not be successful in consummating the Merger or any other strategic transaction or they may not deliver the value to our shareholders that we anticipate.

Based on the results of the Phase 3 OVAL clinical trial, we began exploring strategic alternatives to enhance shareholder value and engaged Chardan as our exclusive financial advisor to assist in this process. The strategic alternatives that we explored included some or all of the following: license, divestiture, or monetization of current assets; license or acquisition of additional assets; merger, reverse merger, joint venture, partnership, or other business combination with another entity, public or private.

Following this review process, on February 15, 2023, we entered into an asset purchase agreement providing for the sale of our rights to lease the Modi'in facility and certain related assets (which sale closed on March 9, 2023). Further, on February 22, 2023, we entered into the Merger Agreement, pursuant to which, and subject to the satisfaction or waiver of the conditions set forth therein, Notable will become our wholly-owned subsidiary and its management and stockholders will control our company and its financial statements will become our financial statements under applicable accounting rules. There can be no assurance that we will be able to successfully consummate the proposed Merger on a timely basis or at all, or that this transaction as well as any transaction we may pursue for VB-601, will successfully enhance shareholder value. If we are unable to execute on this or other strategic alternatives, we may be forced to liquidate.

The process of pursuing these or any other strategic alternatives could adversely impact our business, financial condition and results of operations and we have incurred and will continue to incur substantial expenses associated with these processes, including those related to equity compensation, severance pay and insurance, legal, accounting and financial advisory fees. In addition, the process is time consuming and may be disruptive to our business operations, could divert the attention of management and the board of directors from our business, has led to additional resignations from our workforce and could interfere with our ability to retain our remaining employees, and could expose us to potential litigation in connection with this process or any resulting transaction. Further, speculation regarding any developments related to the consummation of our strategic alternatives and perceived uncertainties related to our future could cause our stock price to fluctuate significantly.

We may need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Developing pharmaceutical products is expensive, and we expect our research and development expenses to increase substantially in connection with any expanded activities, particularly as we advance any product candidate in clinical trials.

As of December 31, 2022, our cash and cash equivalents, restricted cash, and short-term bank deposits were $21.1 million. We estimate that the balance of cash, cash equivalents, restricted cash, and short-term bank deposits be sufficient to fund our operations for at least 12 months from the date of this filing and , together with the proceeds from the sale of rights to lease the Modi'in facility and certain related assets, meet our minimum cash requirements in the Merger Agreement. However, our operating plan may change as a result of many factors including our ability to consummate the Merger or the asset sale, and we may need to seek additional funds sooner than planned through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. In any event, even if we can complete the Merger and sale of our rights, we will require additional capital to obtain regulatory approval for any product candidate, and commercialize and market any product that receives regulatory approval. Raising funds in the current economic environment may present additional challenges. Global health concerns resulting from the outbreak of the coronavirus and worldwide macroeconomic turmoil may have long-term lasting effects on our ability to raise capital, many of which are difficult for us to predict at this time. Even if we believe we have sufficient funds for our current or potential future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may compromise our ability to develop and commercialize any product candidate. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ordinary shares to decline. The sale of additional equity or convertible securities would dilute all of our shareholders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than would be desirable, and we may be required to relinquish rights to our technology or product candidate or otherwise agree to terms unfavorable to us.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue our research or development program or the commercialization of any product candidate, and we may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired. We may also need to curtail or cease operations.

We have received Israeli governmental grants to assist in the funding of our research and development activities. If we monetize the programs funded by these grants, we would owe royalties and other payments which could harm our operating results.

Through December 31, 2022 we had received an aggregate of $29.4 million in grants from the Israeli Innovation Authority, or IIA. Under the Israel Encouragement of Research and Development in Industries, or the Research Law, royalties of 3% to 3.5% on the revenues derived from sales of products or services developed in whole or in part using these IIA grants are payable to the Israeli government. The maximum aggregate royalties paid for each technology or program separately, generally cannot exceed 100% of the grants made to us for such technology or program, plus annual interest. We developed ofra-vec and another previously developed program utilizing IIA funds, neither of which we expect to be able to commercialize, and would therefore do not expect to be liable for repayment of such grants. As of December 31, 2022, the balance of the principal and interest in respect of our commitments for these potential future payments to the IIA totaled approximately $38.4 million. To date, we have paid the IIA in relation to our license agreement, royalties of approximately $0.6 million. If we monetize the programs funded by these grants, we would owe royalties and other payments, which could harm our operating results.

The Israeli government grants we have received for research and development expenditures restrict our ability to manufacture product candidates and transfer technologies outside of Israel and require us to satisfy certain conditions. If we fail to satisfy these conditions, we may be required to refund grants previously received together with interest and penalties.

Under the Research Law, we are required to manufacture the majority of any product candidate developed using these grants in the State of Israel or otherwise ask for special approvals. We may not receive the required approvals for any proposed transfer of manufacturing activities outside of Israel. Even if we do receive approval to manufacture a product candidate developed with government grants outside of Israel, the royalty rate may be increased and we may be required to pay up to 300% of the grant amounts plus interest, depending on the manufacturing volume that is performed outside of Israel. This restriction may impair our ability to outsource manufacturing or engage in our own manufacturing operations for those product candidates or technologies. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” for additional information.

Additionally, under the Research Law, we are prohibited from transferring, including by way of license, the IIA-financed technologies and related intellectual property rights and know-how outside of the State of Israel, except under limited circumstances and only with the approval of the IIA Research Committee. We may not receive the required approvals for any proposed transfer and, even if received, we may be required to pay the IIA a portion, to be set by the IIA upon their approval of such transaction, of the consideration or milestone and royalties payments that we receive upon any sale or out licensing of such technology to a non-Israeli entity, up to 600% of the grant amounts plus interest. The scope of the support received, the royalties that we have already paid to the IIA, the amount of time that has elapsed between the date on which the know-how or the related intellectual property rights were transferred and the date on which the IIA grants were received and the sale price and the form of transaction will be taken into account in order to calculate the amount of the payments to the IIA. For Israeli entities, approval of the transfer of technology to residents of the State of Israel is required, and may be granted in specific circumstances only if the recipient abides by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties. No assurance can be made that approval to any such transfer, if requested, will be granted.

These restrictions may impair our ability to sell our technology assets or to perform or outsource manufacturing outside of Israel, engage in change of control transactions or otherwise transfer our know-how outside of Israel and may require us to obtain the approval of the IIA for certain actions and transactions and pay additional royalties and other amounts to the IIA. In addition, any change of control and any change of ownership of our ordinary shares that would make a non-Israeli citizen or resident an “interested party,” as defined in the Research Law, requires prior written notice to the IIA, and our failure to comply with this requirement could result in criminal liability.

These restrictions will continue to apply even after we have repaid the full amount of royalties on the grants. For the years ended December 31, 2022, 2021 and 2020, we recorded grants totaling $0.05 million, $0.5 million and $1.5 million from the IIA, respectively. If we fail to satisfy the conditions of the Research Law, we may be required to refund certain grants previously received together with interest and penalties, and may become subject to criminal charges.

We may not receive the full €2.5 million grant from the Horizon Europe EIC Accelerator Program, which funding is subject to a lengthy process prior to receipt and which we may not successfully achieve, particularly in light of our decision to terminate the ofra-vec program and pursue the Merger with Notable.

On December 20, 2021, we announced that we had been selected for €17.5 million of blended funding by the EIC Accelerator. The funding is comprised of a €2.5 million grant and an additional €15 million direct equity investment by the EIC. To date, we have received $1.1 million, and have performed activities as part of the project of an additional $1.4 million. The funding is subject to meeting the specific requirements of the program and there can be no assurance that we meet and will continue to meet these requirements in order to receive the final grant funding amount. We will not be pursuing the additional €15 million direct equity investment by the EIC due to the OVAL trial outcome and termination of the ofra-vec program.

Risks Related to the Discovery and Development of Our Product Candidate and Platform Technology

We are highly dependent on the success of VB-601 in inflammatory indications, and our platform technology in general, and we cannot be certain that either will receive regulatory approval or be commercialized. Any failure to successfully develop, obtain regulatory approval for and commercialize VB-601 for inflammatory indications, or any other product candidates, independently or in cooperation with a third party collaborator, or the experience of significant delays in doing so, would compromise our ability to generate revenue and become profitable.

We have spent time, money and effort on the development of our platform technology and product candidate VB-601. To date, we have not received regulatory approval for any current and historical product candidates. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory approvals will be obtained.

Our ability to generate product revenue from any product candidate depends heavily on the successful development and commercialization of our product candidate, which, in turn, depends on several factors, including the following:

- successfully enrolling and completing any planned and future trials for VB-601 or any future product candidates;
- our ability to raise additional funding sufficient to conduct future clinical trials and commercialization of a product candidate, if approved;
- demonstrating that VB-601 or any future product candidates are safe and effective at a sufficient level of statistical or clinical significance and otherwise obtaining marketing approvals from regulatory authorities;
- manufacturing our product candidate in large scale and qualifying such processes in compliance with the regulatory requirements for clinical and commercial supply;
- establishing successful manufacturing arrangements with third-party manufacturers that are compliant with cGMP requirements to ensure adequate supply of VB-601 and any future product candidates for clinical development and commercial use, if approved;
- establishing successful sales and marketing arrangements for VB-601 and any future product candidates, if approved;
- maintaining an acceptable safety and efficacy profile for our product candidates;
- the availability of coverage and reimbursement to patients from healthcare payers for our VB-601 and any future product candidates, if approved; and
- other risks described in these “Risk Factors.”

Our product candidate is based on novel technology, which makes it difficult to predict the time and cost of product candidate development and potential regulatory approval.

We have historically concentrated our product research and development efforts on our distinct platform technologies, and our future success depends on the successful development of our technology. We could experience development problems in the future related to our technology, which could cause significant delays or unanticipated costs, and we may not be able to solve such development problems. We may also experience delays in developing sustainable, reproducible and scalable manufacturing processes or transferring those processes to commercial partners, if we decide to do so, which may prevent us from completing our clinical trials or commercializing our product, if approved, on a timely or profitable basis, if at all. If an issue is identified in our platform technology, it may cause us to cease development of the product candidate that utilizes the underlying technology.

In addition, the clinical trial requirements of the FDA, the EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for a novel product candidate such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the FDA may not be indicative of what the EMA or other regulatory agencies may require for approval, and vice versa.

In addition, adverse developments in clinical trials of pharmaceutical products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any product candidate.

These regulatory agencies and review committees and the new requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of a treatment candidate or lead to significant post-approval limitations or restrictions. As we advance our product candidate, we will be required to consult with these regulatory groups, and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidate. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could impair our ability to generate product revenue and to become profitable.

We may find it difficult to enroll patients in our clinical trials, and patients could discontinue their participation in our clinical trials, which could delay or prevent clinical trials of our product candidate.

Identifying and qualifying patients to participate in clinical trials of our product candidate is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. We have experienced delays in some of our previous clinical trials, and we may experience similar delays in the future. If patients are unwilling to participate in our clinical trials because of negative publicity from adverse events in the biotechnology or pharmaceutical industries or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study, and specifically in reference to studies in other indications, with the same product;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

In particular, some of the indications we may develop our candidates for may be for rare disorders with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials will further limit the pool of available trial participants. Additionally, the process of finding and diagnosing patients may prove costly.

We plan to seek initial marketing approval in established global markets, in addition to the United States. We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by the EMA or other foreign regulatory agencies. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CRO and physicians;
- different standards for the conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials, we may need to delay, limit or terminate ongoing or planned clinical trials.

In addition, patients enrolled in our clinical trials may discontinue their participation at any time during the trial as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be judged related to our product candidate under evaluation. The discontinuation of patients in any one of our trials may cause us to delay or abandon our clinical trial, or cause the results from that trial not to be positive or sufficient to support a filing for regulatory approval of the applicable product candidate.

We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of a product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all, and that the trial will result in a positive outcome. For example, our Phase 3 clinical trial of ofra-vec in platinum-resistant ovarian cancer did not successfully meet either primary endpoint, PFS or OS, and we made the decision to cease development of ofra-vec in August 2022. We also cannot guarantee that we will receive regulatory approval if we achieve statistical significance absent clinically meaningful benefit in a confirmatory trial. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory agencies on trial design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required IRB or ethics committee approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials including in particular for those trials for rare diseases;
- delays in clinical trial supply, due to manufacturing delays or other issues;
- imposition of a clinical hold by regulatory agencies, including due to safety reasons with either our product candidate or other product candidates in the same class or after an inspection of our clinical trial operations or trial sites;
- failure by our CROs, other third parties or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's GCP requirements or applicable regulatory requirements in other countries;
- delays in the testing, validation, manufacturing and delivery of our product candidate to the clinical sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites or patients dropping out of a trial;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical trial protocols.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from product sales. In addition, if we make manufacturing or formulation changes to our product candidate, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidate or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates.

If the results of our clinical trials are inconclusive or if there are safety concerns or adverse events associated with any product candidate, we may:

- fail to obtain, or be delayed in obtaining, marketing approval for our product candidate;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- need to change the way the product is administered;
- be unable to compete with other approved products;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution or use in the form of a REMS or modified REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidate and impair our ability to commercialize our product candidate.

Side effects may occur following treatment with our product candidate, which could make it more difficult for our product candidate to receive regulatory approval.

Treatment with our product candidate may cause side effects or adverse events. In addition, because our product candidate may in some cases be administered in combination with other therapies, patients or clinical trial participants may experience side effects or other adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials. Additionally, our product candidates could potentially cause other unforeseen adverse events that we cannot predict. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or the severity of the medical condition treated. The experience of side effects and adverse events in our clinical trials could make it more difficult to achieve regulatory approval of our product candidate, if at all, or could negatively impact the market acceptance of such products, if approved.

Success in early and prior clinical trials may not be indicative of results obtained in later trials.

There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage and prior clinical trials. The results of nonclinical and preclinical studies and clinical trials may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. The results of preclinical studies and clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures and timing of such procedures as set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and the rate of dropout among clinical trial participants, among other factors. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

The results from our future clinical trials may not be sufficiently robust to support the submission for marketing approval for our product candidate. Before we submit any product candidate for marketing approval, the FDA and the EMA may require us to conduct additional clinical trials, or evaluate subjects for an additional follow-up period.

It is possible that, even if we achieve favorable results in our clinical trials, the FDA or the EMA may require us to conduct additional clinical trials, possibly involving a larger sample size or a different clinical trial design, particularly if the FDA or the EMA does not find the results from our completed clinical trials to be sufficiently persuasive to support a BLA or an NDA. For example, achieving statistical significance is no guarantee of approval if there is no clinically meaningful benefit.

It is also possible that the FDA or the EMA may not consider the results of our clinical trials to be sufficient for approval of our product candidate for its target indications. If the FDA or the EMA requires additional studies for any reason, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, it is possible that the FDA and the EMA may have divergent opinions on the elements necessary for a successful NDA or BLA and Marketing Authorisation Application, which is the equivalent of an NDA and BLA, respectively, which may cause us to alter our development, regulatory or commercialization strategies.

Even if we complete the necessary preclinical studies and clinical trials, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate or the approval may be for a more narrow indication than we expect.

We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidate demonstrates safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA advisory committee or other regulatory authority recommends non-approval or restrictions on approval, or if the FDA is unable to conduct a timely inspection of our third party manufacturing facility. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Regulatory agencies also may approve a treatment candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our treatment candidates.

Even if we obtain regulatory approval for a product candidate, our product will remain subject to regulatory scrutiny.

Even if we obtain regulatory approval in a jurisdiction, the regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product candidate, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The FDA may also impose a REMS which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product sponsors and their manufacturers and manufacturing facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP and other regulatory requirements, such as product tracking and tracing, and adherence to commitments made in the BLA as the case may be. If we or a regulatory agency discover previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any product candidate, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval or suspend or revoke a license;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or supplements to a BLA submitted by us for other indications or new biological products;
- impose restrictions on the marketing or manufacturing of our product;
- seize our product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidate and generate revenues.

We have only limited experience in regulatory affairs and intend to rely on consultants and other third parties for regulatory matters, which may affect our ability or the time we require to obtain necessary regulatory approvals.

We have limited experience in filing and prosecuting the applications necessary to gain regulatory approvals for investigational product candidates. We intend to rely on independent consultants for purposes of our regulatory compliance and product development and approvals in the United States and elsewhere. Any failure by our consultants to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements could compromise our ability to develop and seek regulatory approval of our product candidate.

In addition to the level of commercial success of our product candidate, if approved, our future prospects are also dependent on our ability to successfully develop a pipeline of additional product candidates, and we may not be successful in our efforts in using our platform to identify or discover additional product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates based on our platform technology. Our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. We may also be limited in our ability to pursue multiple indications with any one product candidate, due to financial or other resource constraints, development issues or regulatory obstacles.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs. For example, we ceased development of ofra-vec in August 2022 after its Phase 3 trial in platinum-resistant ovarian cancer did not meet its primary endpoints. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

Risks Related to Our Reliance on Third Parties

We expect to rely on third parties to conduct some or all aspects of our product manufacturing, protocol development, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We do not expect to independently conduct all aspects of our product manufacturing, protocol development, research and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties with respect to these items.

We do not have the ability to independently conduct clinical trials. We rely and expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidate. We may also rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to a product candidate. We will not control the design or conduct of any investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, and we may not own the data from certain investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidate. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidate, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For example, for a product candidate that we develop and commercialize on our own, we will remain responsible for ensuring that each of our IND-enabling studies and clinical trials are conducted in accordance with the study plan and protocols. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the preclinical studies and clinical trials required to support future IND submissions and approval of our product candidates.

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

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

We and our CDMOs are subject to significant regulation with respect to manufacturing our product candidate. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

We currently have relationships with a limited number of suppliers for the manufacturing of our product candidate. Each supplier may require licenses to manufacture components of our product candidate or to utilize certain processes for the manufacture of our product candidate. If such components or licenses are not owned by the supplier or in the public domain, we may be unable to transfer or sublicense the intellectual property rights we may have with respect to such activities.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidate, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidate that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA, as applicable, on a timely basis and must adhere to the FDA's cGMP regulations enforced by the FDA through its facilities inspection program. Information requests from the FDA or failure to meet FDA requirements can result in delays in clinical trials, and any future commercial supply. The facilities and controls of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidate or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidate or our other potential products or the associated controls for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA or other regulatory authority approval of the product candidate will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or our product specifications, or if a violation of applicable regulations, including a failure to comply with the product specifications, occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product, or revocation of a pre-existing approval.

If any manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product or product candidate may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop a product candidate or commercialize a product in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trial and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Additionally, if any of our product candidate receives regulatory approval and supply from a manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA supplement which could result in further delay. The regulatory agencies may also require comparability studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, supplier delays, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMP requirements, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any product candidate or any future product candidates, there is no assurance that we or our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If we or our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of a product candidate, cause us to incur higher costs and prevent us from commercializing our product successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials and potential commercialization may be delayed or we could lose potential revenue.

We have relied, and expect to continue to rely on third parties to conduct, supervise and monitor our clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We have relied, and expect to continue to rely on CROs and clinical trial sites, including clinical investigators, to ensure our clinical trials are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only some aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific requirements and standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's GCP requirements for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GCP requirements through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCP requirements. In addition, our clinical trials will require a sufficient number of test subjects to evaluate the safety and effectiveness of a product candidate. Recruitment in rare diseases may be challenging and require the performance of trials in a significant number of sites which may be harder to monitor. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would result in significant additional costs and delay the regulatory approval process.

Our CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including parties developing potentially competitive products, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, 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 regulatory requirements, or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidate would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We also expect to rely on other third parties to store and distribute our product candidate for any clinical trials that we may conduct. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidate or commercialization of our product candidate, if approved, producing additional losses and depriving us of potential product revenue.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our product candidate, and because we collaborate with various organizations and academic institutions on the advancement of our technology, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by potential competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, discovery by a third party of our trade secrets or other unauthorized use or disclosure would impair our intellectual property rights and protections in any product candidate.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication.

Risks Related to Our Business Operations

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team, including Prof. Dror Harats, our chief executive officer, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our named executive officers and have provided for additional retention benefits as we pursue strategic alternatives, any of them could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. Our recent reduction in force and uncertainty around our pursuit of strategic alternatives has resulted in significant employee turnover and difficulty retaining staff. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets and greater financial resources than us. In addition, failure to succeed in preclinical studies or clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development and strategic objectives.

Our collaborations with outside scientists and consultants may be subject to restriction and change.

We work with medical experts, chemists, biologists and other scientists at academic and other institutions, and consultants who assist us in our research, development and regulatory efforts, including the members of our scientific advisory board. In addition, these scientists and consultants have provided, and we expect that they will continue to provide, valuable advice regarding our programs and regulatory approval processes. These scientists and consultants are not our employees and may have other commitments that would limit their future availability to us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we are limited in our ability to prevent them from establishing competing businesses or developing competing products. For example, if a key scientist acting as a principal investigator in any of our clinical trials identifies a potential product or compound that is more scientifically interesting to his or her professional interests, his or her availability to remain involved in our clinical trials could be restricted or eliminated.

We are experiencing difficulties retaining employees, which could disrupt our operations.

As of March 1, 2023, we had seven employees. Our recent reduction in force and uncertainty around our pursuit of strategic alternatives has resulted in significant employee turnover and difficulty retaining staff. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time retaining employees. We may not be able to effectively manage our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage our staff, our expenses may increase more than expected, our ability to generate or grow revenue could be compromised, and we may not be able to implement our business strategy. Our future financial performance and our ability to and compete effectively will depend, in part, on our ability to effectively manage any future operational growth.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our business was negatively impacted by the ongoing COVID-19 pandemic and may in the future be impacted by any future pandemics. In addition, this pandemic may continue to, and any future pandemics may, adversely impact economies worldwide, which could result in adverse effects on our business and operations.

We experienced disruptions in our business as we and our CROs navigated the initial outbreak and subsequent governmental restrictions imposed due to the ongoing COVID-19 pandemic. Although our employees have returned to work, there are a number of vaccines available, and many restrictions have been lifted, there is still uncertainty about the overall impact of COVID-19 on our business, as well as its continuing impact on economies worldwide. Future pandemics may arise, and they, like the COVID-19 pandemic, could impact our company and our CDMOs and CROs, creating disruptions that affect our ability to initiate and complete preclinical studies or clinical trials, disrupt our supply chain for our research and development activities, and disrupt any planned or ongoing clinical trials for any number of reasons. Any future pandemics could similarly impact patient recruitment or retention for clinical trials, or result in resources being redirected in a way that adversely impacts our ability to progress regulatory approvals and protect our intellectual property. In addition, as with the COVID-19 pandemic, we may face impediments to regulatory meetings and approvals due to recommended safety measures intended to limit in-person interactions in any future pandemic.

The ongoing COVID-19 pandemic already caused significant disruptions in the financial markets, and it may continue to, and any future pandemic could similarly, cause such disruptions, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our ordinary shares. We cannot be certain what the overall impact of the ongoing COVID-19 pandemic or any future pandemic will be on our business. The extent of the impact of COVID-19 and any future pandemic on our business, financial condition, results of operations and prospects will depend on future developments that are uncertain.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Separately, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold due to the COVID-19 pandemic, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidate harms patients, or is perceived to harm patients even when such harm is unrelated to our product candidate, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidate. There is a risk that our product candidate may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize a product candidate;
- decreased demand for a product candidate, if approved for commercial sale; and
- impairment of our ability to obtain product liability insurance coverage.

We carry combined public and products liability (including human clinical trials extension) insurance. We believe our product liability insurance coverage is sufficient in light of our current status; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any product candidate, we intend to expand our insurance coverage to include the sale of commercial products, but we may not be able to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. 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 materially and adversely affect our financial position.

Patients with the diseases targeted by some of our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our product candidate, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may harm our reputation, delay our regulatory approval process, limit the type of regulatory approvals our product candidates receive or maintain, and compromise the market acceptance of any of our product candidates that receive regulatory approval. As a result of these factors, a product liability claim, even if successfully defended, could hurt our business and impair our ability to generate revenue.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have very limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates may not yield any commercially viable products. For example, we devoted significant time and effort, as well as capital, on the development of ofra-vec, only to not meet the primary endpoint in the OVAL trial and we ceased development of the program. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a collaboration arrangement.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will continue to be required to devote substantial time to new compliance initiatives.

As a public company, we will continue to incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq have imposed various requirements on public companies. On January 1, 2023, we ceased to be a "foreign private issuer" and are now required to comply with U.S. reporting requirements and subject to additional obligations due to our change in status. Shareholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations, as well as the increase in the number of class actions and other securities litigation filed against publicly traded life sciences companies, to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage. While compliance with these additional requirements and the transition from being a foreign private issuer will result in increased costs to us, we cannot accurately predict or estimate at this time the amount of additional costs we may incur as a public company under both U.S. and Israeli laws.

Additionally, we are no longer an "emerging growth company," as defined in the JOBS Act, and are now required to comply with additional disclosure and reporting requirements even though we now also qualify as a "smaller reporting company" due to the loss of foreign private issuer status. These additional reporting requirements may increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to devote substantial time to these public company requirements.

As a "smaller reporting company," we are permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure; and reduced disclosure obligations regarding executive compensation. We have taken advantage of reduced reporting burdens in this Annual Report on Form 10-K. We cannot predict whether investors will find our ordinary shares less attractive if we rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

Moreover, as a smaller reporting company, we are not required to include an auditor attestation regarding our internal control over financial reporting assessment. If we identify material weaknesses in our internal control over financial reporting, if we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of our ordinary shares could be negatively affected. We could also become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources.

Irrespective of compliance with Sections 404(a) and 404(b) of the Sarbanes-Oxley Act, any failure of our internal control could have a material adverse effect on our stated results of operations and harm our reputation. In order to implement changes to our internal control over financial reporting triggered by a failure of those controls, we could experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes.

We are subject to foreign currency exchange risk, and fluctuations between the U.S. dollar and the NIS, the Euro and other non-U.S. currencies may negatively affect our earnings and results of operations.

We operate in a number of different currencies. While the dollar is our functional and reporting currency and investments in our share capital have been denominated in dollars, our financial results may be adversely affected by fluctuations in currency exchange rates as a significant portion of our operating expenses, including our salary-related and manufacturing expenses are denominated in the NIS.

We are exposed to the risks that the NIS may appreciate relative to the dollar, or, if the NIS instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar- denominated results of operations would be adversely affected. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the dollar. Market volatility and currency fluctuations may limit our ability to cost- effectively hedge against our foreign currency exposure and, in addition, our ability to hedge our exposure to currency fluctuations in certain emerging markets may be limited. Hedging strategies may not eliminate our exposure to foreign exchange rate fluctuations and may involve costs and risks of their own, such as devotion of management time, external costs to implement the strategies and potential accounting implications. Foreign currency fluctuations, independent of the performance of our underlying business, could lead to materially adverse results or could lead to positive results that are not repeated in future periods.

Under applicable employment laws, we may not be able to enforce covenants not to compete.

We generally enter into non-competition agreements with our employees. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period. 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 labor 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 protection of a company's trade secrets or other intellectual property. We have expanded operations into the United States and entered into U.S. employment agreements. As employment law varies from U.S. state to state, we may not be able to enforce non-compete rights in such agreements if U.S. employees reside in states that do not recognize such rights.

Our internal information technology systems, or those of our third-party CROs, contractors, consultants or others who process sensitive information on our behalf, may fail or suffer security incidents, loss or leakage of data and other compromises, any of which could result in a material disruption of our product candidate's development program, compromise sensitive information related to our business or prevent us from accessing such information, expose us to liability or otherwise adversely affect our business.

In the ordinary course of our business, we may collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information (including health information). It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such information. We also have outsourced certain of our operations to third parties, and as a result we manage a number of third parties who have access to our information. Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks by sophisticated nation-state and nation-state supported actors or by malicious third parties (including the deployment of harmful malware (such as malicious code, viruses and worms), natural disasters, global pandemics, fire, terrorism, war and telecommunication and electrical failures, fraudulent activity, as well as security incidents from inadvertent or intentional actions (such as error or theft) by our employees, contractors, consultants, business partners, and/or other third parties, phishing attacks, ransomware, denial-of-service attacks, social engineering schemes and other means that affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure as well as lead to unauthorized access, disclosure or acquisition of information. Cyberattacks are increasing in their frequency, sophistication and intensity. The techniques used to sabotage or to obtain unauthorized access to our information technology systems or those upon whom we rely on to process our information change frequently, and we may be unable to anticipate such techniques or implement adequate preventative measures or to stop security incidents in all instances. The recovery systems, security protocols, network protection mechanisms and other security measures that we have integrated into our information technology systems, which are designed to protect against, detect and minimize security breaches, may not be adequate to prevent or detect service interruption, system failure or data loss.

Significant disruptions of our information technology systems or security incidents could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information including health information), and could result in financial, legal, business and reputational harm to us. If such disruptions were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security incident results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our future product candidates could be delayed.

We may also be required to comply with laws, regulations, rules, industry standards, and other legal obligations that require us to maintain the security of personal data. We may also have contractual and other legal obligations to notify collaborators, our clinical trial participants, or other relevant stakeholders of security incidents. Failure to prevent or mitigate cyberattacks could result in unauthorized access to data, including personal data. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. Such disclosures are costly, could lead to negative publicity, may cause our collaborators or other relevant stakeholders to lose confidence in the effectiveness of our security measures and require us to expend significant capital and other resources to respond to and/or alleviate problems caused by the actual or perceived security breach. In addition, the costs to respond to a cybersecurity event or to mitigate any identified security vulnerabilities could be significant, including costs for remediating the effects of such an event, paying a ransom, restoring data from backups, and conducting data analysis to determine what data may have been affected by the breach. In addition, our efforts to contain or remediate a security incident or any vulnerability exploited to cause an incident may be unsuccessful, and efforts and any related failures to contain or remediate them could result in interruptions, delays, harm to our reputation, and increases to our insurance coverage.

In addition, litigation resulting from security breaches may adversely affect our business. Unauthorized access to our information technology systems could result in litigation with our collaborators, our clinical trial participants, or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur and the confidentiality, integrity or availability of our data or the data of our collaborators were disrupted, we could incur significant liability, which could negatively affect our business and damage our reputation.

Furthermore, we may not have adequate insurance coverage or otherwise protect us from, or adequately mitigate, liabilities or damages. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to obtain exclusivity for our product candidates or prevent others from developing similar competitive products.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in the patent claims being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties and materially affect our operations and financial condition.

If the patent applications we hold with respect to our programs or product candidates fail to issue, if the breadth or strength of our patent protection is threatened, or if our patent portfolio fails to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize future products. Several patent applications covering our product candidates have been filed recently. We cannot offer any assurances about which, if any, applications will issue as patents, the breadth of any such issued patent claims or whether any issued claims will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications. This risk is material in light of the length of the development process of our products and lifespan of our current patent portfolio.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes review proceedings before the U.S. Patent and Trademark Office, or U.S. PTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to pharmaceutical product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have rights to the intellectual property, through licenses from Janssen Vaccines & Prevention B.V. and under patents that we own, to develop our product candidates. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We may enter into license agreements with third parties, and if we fail to comply with our obligations in such agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates.

In many cases, patent prosecution of our in-licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In some cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the trading price of our ordinary shares.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Patent reform legislation continues to increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act introduced a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and patent litigation is conducted. The U.S. PTO continues to develop regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated therewith, in particular, the inter partes review proceedings. It remains to be seen what impact the Leahy-Smith Act will have on the operation of our business. However, its implementation increases the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Certain of our key employees and personnel are or were previously employed at universities, medical institutions or other biotechnology or pharmaceutical companies, including our competitors or potential competitors.

Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Furthermore, universities or medical institutions who employ some of our key employees and personnel in parallel to their engagement by us may claim that intellectual property developed by such person is owned by the respective academic or medical institution under the respective institution intellectual property policy or applicable law.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967, or the Patent Law, inventions conceived by an employee during the term and as part of the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his inventions. Recent decisions by the Committee (which have been upheld by the Israeli Supreme Court on appeal) have created uncertainty in this area, as it held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. Further, the Committee has not yet determined the method for calculating this remuneration nor the criteria or circumstances under which an employee's waiver of his right to remuneration will be disregarded. We generally enter into assignment-of-invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current or former employees, or be forced to litigate such claims, which could negatively affect our business.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may have in the future, ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, 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.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The U.S. PTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court. Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in some situations. 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 the U.S. Congress, the federal courts, and the U.S. PTO, the laws and regulations governing patents 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 have not yet registered trademarks for a commercial trade name for some of our product candidates and failure to secure such registrations could adversely affect our business.

We have not yet registered trademarks for a commercial trade name for some of our product candidates. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the U.S. PTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Potential competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, if approved, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, 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. 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, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. 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.

Risks Related to Ownership of Our Ordinary Shares

The market price of our ordinary shares may be highly volatile, and you may not be able to resell your shares at the purchase price.

An active trading market for our ordinary shares may not be available. You may not be able to sell your shares quickly or at the market price if trading in our ordinary shares is not active.

The market price of our ordinary shares has been and is likely to remain volatile. Our share price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in preclinical studies or clinical trials, and resulting changes in our clinical development programs;
- reports of adverse events in other similar products or clinical trials of such products;
- inability to obtain additional funding or funding on acceptable terms or such time as it would be required;
- any delay in filing an IND or BLA for any product candidate and any adverse development or perceived adverse development with respect to the FDA's review of that IND or BLA;
- failure to develop successfully and commercialize a product candidate for the proposed indications and future product candidates for other indications or new candidates;
- failure to maintain our licensing arrangements or enter into strategic collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to future products;

- inability or delay in scaling up our manufacturing capabilities, inability to obtain adequate product supply for a product candidate or the inability to do so at acceptable prices;
- adverse regulatory decisions, including by the IIA under the Research Law;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed the estimates, expectations, and projections of the investment community and our shareholders;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us (such as the Merger or the recent sale of our rights to lease the Modi'in facility) or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or shareholder litigation;
- changes in the market valuations of similar companies;
- general economic and market conditions and overall fluctuations in the U.S. equity market;
- any identified material weakness in our internal control over financial reporting;
- changes in the Nasdaq listing of our stock;
- recommendations of equity analysts covering our stock;
- the outcome of our strategic processes;
- sales of our ordinary shares by us or our shareholders in the future; and
- trading volume of our ordinary shares.

In addition, companies trading in the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ordinary shares, regardless of our actual operating performance.

There has been limited trading volume for our ordinary shares.

Even though our ordinary shares have been listed on Nasdaq, there has been limited liquidity in the market for the ordinary shares, which could make it more difficult for holders to sell their ordinary shares. There can be no assurance that an active trading market for our ordinary shares will be sustained. In addition, the stock market generally has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may negatively affect the market price of our ordinary shares, regardless of our actual operating performance. The market price and liquidity of the market for our ordinary shares that will prevail in the market may be higher or lower than the price you pay and may be significantly affected by numerous factors, some of which are beyond our control.

Our principal shareholders and management own a significant percentage of our shares and will be able to exert significant control over matters subject to shareholder approval.

As of December 31, 2022, to the best of our information, our executive officers, key management, directors, 5% shareholders and their affiliates beneficially owned approximately 32% of our voting shares. Therefore, these shareholders have the ability to influence us through their ownership positions. These shareholders may be able to determine all matters requiring shareholder approval. For example, these shareholders, if they were to act together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares that you may believe are in your best interest as one of our shareholders.

Future sales and issuances of our ordinary shares or rights to purchase ordinary shares, including pursuant to our equity incentive plans and at-the-market offering, could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. We may sell ordinary shares, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time, including pursuant to the at-the-market facility with Jefferies LLC, or the Jefferies ATM. If we sell ordinary shares, convertible securities or other equity securities in one or more transactions, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

We also have equity plans that provide for the grant of share options and other equity-based awards to our employees, directors and consultants, and have issued warrants. The exercise of any of these options and warrants would result in additional share issuances and may be dilutive. As these securities are registered, many are available for resale into the public market. Sales of a substantial number of shares of our ordinary shares by our existing shareholders in the public market, or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our ordinary shares.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. In July 2022 we announced the OVAL Phase 3 trial did not meet its primary endpoint, which resulted in a significant reduction in our share price and increase the volatility of our ordinary shares. We are also now pursuing the Merger, exploring options for VB-601 and recently completed the sale of our rights to lease the Modi'in facility, which transactions may not maximize shareholder value as intended. If we face any such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We do not intend to pay dividends on our ordinary shares in the foreseeable future, so any returns will be limited to the value of our shares.

We have never declared or paid any cash dividends on our share capital. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to shareholders will therefore be limited to the appreciation of their shares. In addition, Israeli law limits our ability to declare and pay dividends, and may subject our dividends to Israeli withholding taxes. Furthermore, our payment of dividends (out of tax-exempt income) may retroactively subject us to certain Israeli corporate income taxes, to which we would not otherwise be subject.

If equity research analysts do not publish research reports about our business or if they issue unfavorable commentary or downgrade our ordinary shares, the price of our ordinary shares could decline.

The trading market for our ordinary shares relies in part on the research and reports that equity research analysts publish about us and our business. The price of our ordinary shares could decline if we do not obtain research analyst coverage, or one or more securities analysts downgrade our ordinary shares, or if those analysts issue other unfavorable commentary or expectations that we are unable to meet, or cease publishing reports about us or our business.

Risks Related to Our Incorporation and Operations in Israel

We have lost our foreign private issuer status, which requires us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

As a foreign private issuer, we were permitted by the SEC to file an annual report on Form 20-F and copies of certain home country materials on Form 6-K in lieu of filing annual, quarterly and current reports on Forms 10-K, 10-Q and 8-K. We were exempt from SEC proxy statement requirements and certain SEC tender offer requirements and our affiliates are exempt from Section 16 of the Exchange Act.

We ceased to be a foreign private issuer and ceased to be eligible for the foregoing exemptions and privileges effective January 1, 2023. We are required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of January 1, 2023, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. Although we already report under U.S. GAAP and voluntarily publish quarterly financial information, the regulatory and compliance costs to once we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we incur as a foreign private issuer even though we are able to qualify as a "smaller reporting company."

As a result, we expect that our recent loss of foreign private issuer status will increase our legal and financial compliance costs and may make some activities highly time consuming and costly. It will also impose additional burdens on holders of our securities, which may make an investment in our company less attractive. We expect that complying with the rules and regulations applicable to United States domestic issuers may make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

Potential political, economic and military instability in the State of Israel, where the majority of our senior management and employees are located, may adversely affect our results of operations.

We are incorporated under Israeli law and our offices and core operations are located in the State of Israel, with a small operational base in the United States. In addition, most of our key employees and officers and three of our directors are residents of Israel. Accordingly, political, economic and military conditions in Israel directly affect our business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries.

Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or a significant downturn in the economic or financial condition of Israel, could affect adversely our operations. Since October 2000, there have been increasing occurrences of terrorist violence. Ongoing and revived hostilities or other Israeli political or economic factors could harm our operations, product development and results of operations.

In addition, Israel faces threats from more distant neighbors, in particular, Iran. Our insurance policies do not cover us for the damages incurred in connection with these conflicts or for any resulting disruption in our operations. The Israeli government, as a matter of law, provides coverage for the reinstatement value of direct damages that are caused by terrorist attacks or acts of war; however, the government may cease providing such coverage or the coverage might not be enough to cover potential damages. In the event that hostilities disrupt the ongoing operation of our facilities or the airports and seaports on which we depend to import and export our supplies and products, our operations may be materially adversely affected.

In addition, numerous acts of protest and civil unrest have taken place in several countries in the Middle East and North Africa, many of which involved significant violence, including Egypt and Syria, which border Israel. The ultimate effect of these developments on the political and security situation in the Middle East and on Israel's position within the region is not clear at this time. Such instability may lead to deterioration in the political and trade relationships that exist between the State of Israel and certain other countries.

Popular uprisings in various countries in the Middle East and North Africa are affecting the political stability of those countries. Such instability may lead to deterioration in the political and trade relationships that exist between the State of Israel and these countries. Several countries, principally in the Middle East, still restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in Israel or political instability in the region continues or increases. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or significant downturns in the economic or financial condition of Israel, could adversely affect our operations and product development and adversely affect our share price. Similarly, Israeli companies are limited in conducting business with entities from several countries. For instance, in 2008, the Israeli legislature passed a law forbidding any investments in entities that transact business with Iran.

Additionally, the Israeli government is currently advancing significant changes in Israeli legislation concerning judiciary nomination and oversight. If such proposals will be enacted by the Israeli Knesset, they will change the current balance between the three branches of government in Israel in a manner that is expected to add significant power to the executive and the legislative branches. Such changes may have actual or perceived effects regarding the risks associated with conducting business or investing in Israel. Since the proposals have not yet been enacted as law, the uncertainty of their effect on the Company and its business may not be estimated at this time.

Our operations may be disrupted by the obligations of personnel to perform military service.

As of March 1, 2023, we had seven employees, six of whom were based in Israel. Israeli employees may be called upon to perform up to 36 days (and in some cases more) of annual military reserve duty until they reach the age of 40 (and in some cases, up to 45 or older) and, in emergency circumstances, could be called to immediate and unlimited active duty. In the event of severe unrest or other conflict, individuals could be required to serve in the military for extended periods of time. Since September 2000, in response to increased tension and hostilities, there have been occasional call-ups of military reservists and it is possible that there will be additional call-ups in the future. Although our current streamlined workforce does not include any employees subject to this obligation, if our Israeli workforce grows and becomes subject to this duty, it could impact our operations, which disruptions could materially adversely affect our business and results of operations. Additionally, the absence of a significant number of the employees of our Israeli suppliers and contractors related to military service or the absence for extended periods of one or more of their key employees for military service may disrupt their operations.

The tax benefits that are available to us if and when we generate taxable income require us to meet various conditions and may be prevented or reduced in the future, which could increase our costs and taxes.

If and when we generate taxable income, we would be eligible for certain tax benefits provided to "Benefited Enterprises" under the Israeli Law for the Encouragement of Capital Investments, 1959, as amended, or the Investment Law. In order to remain eligible for the tax benefits for "Benefited Enterprises" we must continue to meet certain conditions stipulated in the Investment Law and its regulations, as amended. In addition, we informed the Israeli Tax Authority of our choice of 2012 as a "Benefited Enterprise" election year, all under the Investment Law. The benefits available to us under this tax regulation are subject to the fulfillment of conditions stipulated in the regulation. Further, in the future these tax benefits may be reduced or discontinued. If these tax benefits are reduced, cancelled or discontinued, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies is 23% for 2018 and thereafter. Additionally, if we increase our activities outside of Israel through acquisitions, for example, our expanded activities might not be eligible for inclusion in future Israeli tax benefit programs.

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

We were incorporated in Israel, and our corporate headquarters and substantially all of our operations are located in Israel. Most of our executive officers and three of our directors, and the Israeli experts named in this document, are located in Israel. The majority of our assets and the assets of these persons are located outside the United States. Therefore, it may be difficult for an investor, or any other person or entity, to enforce a U.S. court judgment based upon the civil liability provisions of the U.S. federal securities laws against us or any of these persons in a U.S. or Israeli court, or to effect service of process upon these persons in the United States. Additionally, it may be difficult for an investor, or any other person or entity, to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws against us or our officers and directors on the grounds that Israel is not the most appropriate forum in which to bring such a claim. 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 proved as a fact, 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 addressing the matters described above.

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

Because we are incorporated under Israeli law, the rights and responsibilities of our shareholders are governed by our articles of association and Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders of U.S. corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to the company's articles of association, an increase of the company's authorized share capital, a merger of the company and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from discriminating against other shareholders. In addition, a controlling shareholder or a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of an officer of the company has a duty to act in fairness towards the company with regard to such vote or appointment. 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 nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on our shareholders that are not typically imposed on shareholders of U.S. corporations. See "Item 13. "Certain Relationships and Related Transactions, and Director Independence—Approval of Related Party Transactions Under Israeli Law."

Provisions of Israeli law and our amended and restated articles of association could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our shareholders.

Israeli 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 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 approval of a majority of the offerees that do not have a personal interest in the tender offer, unless at least 98% of the company's outstanding shares are tendered. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer (unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek appraisal rights), 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. See Exhibit 4.1 "Description of Capital Stock—Memorandum and Articles of Association-Acquisitions under Israeli Law" for additional information.

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

Certain U.S. shareholders may be subject to adverse tax consequences if we are characterized as "Controlled Foreign Corporation."

Each "Ten Percent Shareholder" in a non-U.S. corporation that is classified as a "controlled foreign corporation," or a CFC, for U.S. federal income tax purposes generally is required to include in income for U.S. federal tax purposes such Ten Percent Shareholder's pro rata share of the CFC's "Subpart F income" and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. A non-U.S. corporation generally will be classified as a CFC for U.S. federal income tax purposes if Ten Percent Shareholders own, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A "Ten Percent Shareholder" is a U.S. person (as defined by the U.S. Internal Revenue Code of 1986, as amended), who owns or is considered to own 10% or more of the total combined voting power of all classes of stock entitled to vote of such corporation. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain.

We do not believe that we were a CFC for the taxable year ended December 31, 2022 or that we are currently a CFC. It is possible, however, that a shareholder treated as a U.S. person for U.S. federal income tax purposes will acquire, directly or indirectly, enough shares to be treated as a Ten Percent Shareholder after application of the constructive ownership rules and, together with any other Ten Percent Shareholders of our company, cause us to be treated as a CFC for U.S. federal income tax purposes. We believe that certain of our shareholders are Ten Percent Shareholders for U.S. federal income tax purposes. Holders should consult their own tax advisors with respect to the potential adverse U.S. federal income tax consequences of becoming a Ten Percent Shareholder in a CFC.

We might be classified as a passive foreign investment company in future years, and our U.S. shareholders may suffer adverse tax consequences as a result.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of share sales.

Because PFIC status depends on the composition of our income and the composition and value of our assets (which may be determined in part by reference to the market value of our ordinary shares, which may be volatile) from time to time, there can be no assurance that we will not be considered a PFIC for any taxable year. We believe that we were not a PFIC for our 2022 taxable year. However, the determination of whether are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. As a result, there can be no assurance that we will not be treated as a PFIC for the current or any future taxable year.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

Our corporate headquarters are currently located in Modi'in, Israel, where we continue to occupy office space for a nominal fee in our former Modi'in facility that we sold in March 2023. We are evaluating alternative locations to support future operations, as appropriate, for our current needs. We do not anticipate that we will have difficulty finding suitable office space for our streamlined operations as we look to complete the Merger, or if we are unsuccessful in consummating such transaction. We also have a small U.S. office rented on a monthly basis located at 1 Blue Hill Plaza, Suite 1509, Pearl River, NY 10965.

Item 3. LEGAL PROCEEDINGS

From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business. We are currently not party to any legal proceedings that are likely to have a material adverse effect on our results of operations, financial condition or cash flows.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our ordinary shares are listed on the Nasdaq Capital Market under the symbol "VBLT."

We are not currently in compliance with the listing requirements and our ordinary shares could be subject to delisting. See "Item 1A. Risk Factors—*We are not in compliance with Nasdaq's minimum bid price requirement and if we fail to regain compliance with Nasdaq's continued listing requirements, our ordinary shares could be delisted, which could adversely affect the liquidity of our ordinary shares and our ability to raise additional capital or complete the Merger. The Merger is a 'change of control' and the combined company will need to satisfy all of Nasdaq's initial listing criteria to remain listed on Nasdaq*."

Holders of Record

According to our transfer agent, as of March 10, 2023, there were 12 record holders of our ordinary shares. None of our shareholders have different voting rights from other shareholders. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid any cash dividends to our shareholders. We currently anticipate that we will retain all of our future earnings, if any, for use in the operation of our business. Additionally, our ability to pay dividends on our ordinary shares is limited by restrictions under the terms of the agreements governing our indebtedness and under Israeli law.

Recent Sales of Unregistered Securities

In January 2022, we issued 10,362 restricted shares for services provided.

In April 2022, we issued 11,627 restricted shares for services provided.

In July 2022, we issued 12,269 restricted shares for services provided.

Item 6. [RESERVED]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this Annual Report. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. See "Cautionary Note Regarding Forward-Looking Statements." Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Item 1A. Risk Factors" and elsewhere in this Annual Report.

Overview

We are a biopharmaceutical company that has historically focused on developing targeted therapies for immune-inflammatory diseases and cancer. Our goal is to provide differentiated targeted therapeutics to address the underlying cause of diseases where treatment options are limited. Our sole product candidate, VB-601, is a targeted antibody for immune-inflammatory applications that has shown disease-modifying activity across multiple preclinical models including multiple sclerosis, rheumatoid arthritis and inflammatory bowel disease. VB-601 was developed using our monocyte targeting technology, or MTT, and is designed to specifically inhibit monocyte migration. In October 2022, we submitted an application to the Israel Ministry of Health and institutional review board for a first-in-human Phase 1 trial evaluating VB-601 in healthy volunteers. Production of cGMP grade material of VB-601 for the Phase 1 trial was completed using a third party vendor, and the procedures required for study launch are being finalized. Initiation of this trial is subject to the progress and outcome of our corporate strategic process, and we may look to monetize this asset rather than continue development internally.

We commenced operations in 2000, and historically our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our platform technologies and our product candidates, including conducting preclinical studies and clinical trials of ofra-vec and VB-601, and other programs we are no longer pursuing. To date, we have funded our operations through private sales of preferred shares, a convertible loan, public offerings, revenues from licensing agreements, grants from the Israeli Office of Chief Scientist, or OCS, which has later transformed to the IIA under the Research Law, and the European Innovation Commission. We have no products that have received regulatory approval and accordingly have never generated regular revenue streams from sales of our products. Since our inception through December 31, 2022, we had raised an aggregate of $327.0 million to fund our operations, including $29.4 million from IIA grants.

Since inception, we have incurred significant losses. For the years ended December 31, 2022 and 2021, our loss was $32.3 million and $29.9 million, respectively. We expect to continue to incur significant expenses and losses for at least the next several years and increased expenses related to our development programs, including expenses related to initiation of new clinical trials. As of December 31, 2022, we had an accumulated deficit of $294.4 million. Our losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials, the receipt of payments under any future collaborations we may enter into, and our expenditures on other research and development activities.

As of December 31, 2022, we had cash, cash equivalents, short-term bank deposits and restricted bank deposits of $21.1 million. To fund further operations and obtain regulatory approval for our product candidates if we determine to proceed with development, we will need to raise additional capital. We may seek to raise capital to pursue additional activities, which may be through a combination of private and public equity offerings, government grants, strategic collaborations and licensing arrangements. Additional financing may not be available when we specifically need it or may not be available on terms that are favorable to us. As of the date of this Annual Report, we had seven employees.

Recent Developments

Prior to July 2022, our lead candidate was ofra-vec (VB-111), a custom designed therapeutic candidate comprised of a viral vector, promoter, and therapeutic gene. In July 2022, we announced that our Phase 3 OVAL clinical trial did not meet the primary endpoints and subsequently, we ceased further development of ofra-vec in all indications.

In August 2022, we announced a process to explore strategic alternatives to enhance shareholder value and engaged Chardan, as our exclusive financial advisor to assist in this process. Potential strategic options explored or evaluated as part of the process included, but were not limited to merger, reverse merger, other business combination, sale of assets, licensing, or other strategic transactions. We also announced an organizational streamlining designed to reduce operating expenses and preserve capital as we explored strategic options to maximize shareholder value and as a result, to date, have we reduced our workforce by approximately 84% and our board of directors was reduced from nine to six.

Proposed Merger with Notable Labs, Inc.

On February 22, 2023, we entered into the Merger Agreement with Notable and Merger Sub, pursuant to which, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Notable will be merged with and into Merger Sub at the Effective Time, with Notable continuing after the Merger as the surviving corporation and our wholly-owned subsidiary. The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

At the Effective Time, each outstanding share of Notable capital stock will be converted into the right to receive our ordinary shares, as set forth in the Merger Agreement. Under the exchange ratio formula in the Merger Agreement, immediately following the Effective Time, the former Notable securityholders are expected to own approximately 76% of our ordinary shares on a fully diluted basis and subject to adjustment and our securityholders of VBL as of immediately prior to the Effective Time are expected to own approximately 24% of our ordinary shares on a fully diluted basis and subject to adjustment. Under certain circumstances further described in the Merger Agreement, the ownership percentages may be adjusted upward or downward based on the level of our net cash at the closing of the Merger, and the terms and net proceeds of Notable's pre-merger financing. There can be no assurances as to our level of net cash between the signing of the Merger Agreement and the closing of the Merger.

The Merger Agreement also provides that, immediately following the Effective Time, the board of directors of the combined company will consist of up to seven directors, with one director designated by us. Upon the closing of the transaction, the combined company will be led by Notable's chief executive officer and executive management team. In connection with the Merger, we will seek to amend our articles of incorporation to: (i) effect an increase of our registered share capital and/or effect a reverse split of our ordinary shares at a ratio to be determined; (ii) change our name to "Notable Labs, Ltd."; and (iii) make other such changes as mutually agreeable to our company and Notable.

While the accounting treatment of the Merger is not yet finalized, it is expected to be accounted for as a reverse merger, and the historical financial statements of Notable will be our historical financial statements upon completion of the Merger.

For additional information regarding the proposed Merger, see "Item 1. Business—Recent Developments."

Although we have entered into the Merger Agreement and intend to consummate the proposed Merger, there is no assurance that we will be able to successfully consummate the proposed Merger on a timely basis, or at all. If, for any reason, the proposed Merger is not completed, we will reconsider our strategic alternatives and could pursue one or more of the following courses of action:

- Pursue potential collaborative, partnering or other strategic arrangements for our assets, including a sale or other divestiture of VB-601 and any of our other assets; or in-licensing additional programs and assets to develop internally.
- Pursue another strategic transaction like the proposed Merger. Our board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the proposed Merger.
- Dissolve and liquidate our assets. If, for any reason, the proposed Merger is not consummated and we are unable to identify and complete an alternative strategic transaction like the Merger or potential collaborative, partnering or other strategic arrangements for our assets, or to continue to operate our business due to our inability to raise additional funding, we may be required to dissolve and liquidate our assets. In such case, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to our shareholders after paying our debts and other obligations and setting aside funds for reserves.

Sale of Assets in the Modi'in Facility

On February 15, 2023, we entered into the Purchase Agreement providing for the sale of our rights to lease the Modi'in manufacturing facility, along with certain tangible assets and equipment located therein for $7.1 million. We intend to use the proceeds from the asset sale to meet the $15.0 million minimum net cash closing condition provided in the Merger Agreement and are disposing of such rights in contemplation of the Merger (although completion of such asset sale is not a condition to the Merger). There can be no guarantee that we will have sufficient funds to satisfy the minimum net cash closing required pursuant to the Merger Agreement. We closed the asset sale on March 9, 2023. We have retained the right to use a portion of the space for a nominal fee until May 31, 2023.

Financial Overview

Revenues and Cost of Revenues

Since inception, we have generated cumulative revenues of approximately $17.4 million primarily from an exclusive license agreement with Nanocarrier for the development, commercialization, and supply of ofra-vec in Japan for all indications. In light of the determination to discontinue development of ofra-vec in all indications, this license agreement has been terminated and we do not expect to generate additional revenues from the achievement of new milestones or royalties under this agreement. The generated revenues comprise upfront and milestone payments. The cost of revenues associated with these revenues was approximately $1.6 million.

We do not expect to receive any revenue from VB-601 or any product candidates that we develop unless and until we obtain regulatory approval and commercialize our products, meet regulatory milestones in relation to our existing collaborative agreements, or enter into new collaborative agreements with third parties.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of our platform technology and product candidate. Those expenses include:

- employee-related expenses, including salaries and share-based compensation expenses for employees in research and development functions;
- expenses incurred in operating our laboratories and manufacturing facility;
- expenses incurred under agreements with clinical research organizations and investigative sites that conduct our clinical trials;
- expenses relating to outsourced and contracted services, such as external laboratories, consulting and advisory services;
- supply, development and manufacturing costs relating to clinical trial materials;
- maintenance of facilities, depreciation and other expenses, which include direct and allocated expenses for rent and insurance; and
- costs associated with preclinical and clinical activities.

Historically, research and development activities were the primary focus of our business. Our research and development expenses are likely to decrease significantly with the termination of the OVAL study and ofra-vec program, partially offset by an increase of research and development expenses as we move our VB-601 product candidate into clinical development.

Research and development expenses are recognized as incurred. An intangible asset arising from the development of our product candidates is recognized if certain capitalization conditions are met. As of December 31, 2022, we did not have any capitalized development costs.

We have received grants for the ofra-vec program and another historical program from the Israeli Office of Chief Scientist, or OCS, which has later transformed to the Israeli Innovation Authority, or IIA, under the Israel Encouragement of Research and Development in Industry, or the Research Law, as part of the research and development programs. The requirements and restrictions for such grants are found in the Research Law. These grants are subject to repayment through future royalty payments on any products resulting from these research and development programs that received grant funding. The total gross amount of grants actually received by us from the IIA, including accrued interest as of December 31, 2022, totaled $38.4 million.

Under applicable accounting rules, grants from the IIA have been accounted for as an off-set against the related research and development expenses in our financial statements. As a result, our research and development expenses are shown on our financial statements net of the IIA grants.

In August 2022, we received $1.1 million as part of the grant from the European Innovation Council, or EIC, for development of ofra-vec. The grant has been accounted for as an off-set against the related research and development expenses in the financial statements. We may be entitled to an additional $1.4 million in grant funds for project activities conducted prior to the termination of the ofra-vec project; however, there can be no assurance that we will receive these funds.

Due to the closure of our ofra-vec program, early nature of the VB-601 program, and our strategic process, we expect research and development expenses to be significantly less than prior periods.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive and finance functions such as salaries, benefits and share-based compensation. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, communication expenses, and professional fees for legal services, patents and portfolio maintenance, consulting, commercialization, auditing and accounting services. Given the significant reduction in our workforce, we expect our general and administrative expenses for personnel to decrease.

Financial Expenses (Income), Net

Financial income is comprised of interest income generated from interest earned on our cash, cash equivalents and short-term bank deposits and gains and losses due to fluctuations in foreign currency exchange rates, mainly in the appreciation and depreciation of the NIS exchange rate against the U.S. dollar.

Financial expenses primarily consist of calculated interest expenses from our lease liabilities and gains and losses due to fluctuations in foreign currency exchange rates.

Taxes on Income

We have not generated taxable income since our inception and had carry forward tax losses as of December 31, 2022, of $250.5 million. We anticipate that we will be able to carry forward these tax losses indefinitely to future tax years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses.

We recognize full valuation allowance because we do not expect taxable income.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures in the financial statements. Critical accounting policies are those accounting policies that may be material due to the levels of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change, and that have a material impact on financial condition or operating performance. While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results may differ from these estimates under different assumptions or conditions. Our most critical accounting estimates include the following. For additional information relating to these and other accounting policies, see Note 1 in the Notes to the Financial Statements, appearing elsewhere in this this Annual Report on Form 10-K.

Revenue Recognition

The recognition of revenue under our former NanoCarrier license agreement (which was terminated in 2022) required the exercise of judgment by management. Notably, our management exercised judgment in the following areas:

Identifying the performance obligations in the agreement and determining whether the license provided is distinct - based on our analysis, the license is distinct as the licensee is able to benefit from the license on its own at its current stage (inter alia, due to sublicensing rights, rights and responsibility for development in the territory, etc.).

Allocation of the transaction price - we estimated the standalone selling prices of the services to be provided based on expected cost plus margin and used the residual approach to estimate the standalone selling price of the license as we have not yet established a price for the license, and it has not previously been sold on a standalone basis.

Variable consideration consists of potential future milestone payments. We determined that all such variable consideration shall be allocated to the license (the satisfied performance obligation).

See also Note 7 in the Notes to the Financial Statements.

Share-Based Compensation

With respect to grants to employees, the value is measured on the date of grant based on the fair value of the equity instruments granted to the employees. We determine grant date fair value using the Black-Scholes model, which requires the management to make significant estimates and judgments. See Note 9 in the Notes to the Financial Statements, appearing elsewhere in this this Annual Report on Form 10-K, for information regarding the various assumptions used.

The value of the transactions, measured as aforesaid, is expensed over the period during which the right of the employees and non-employees to exercise or receive the underlying equity instruments vests; commensurate with every periodic recognition of the expense, a corresponding increase is recorded to additional paid in capital, included under our equity (see also Note 9 in the Notes to the Financial Statements).

Results of Operations

Comparison of Years Ended December 31, 2022 and 2021 (in thousands)

	Year ended December 31,		2022 Increase (Decrease)
	2022	2021	$
Revenues	$ 658	768	(110)
Cost of Revenues	(104)	(365)	261
Gross profit	554	403	151
Expenses:			
Research and development, gross	$ 22,814	$ 23,206	$ (392)
Government grants	(1,161)	(511)	(650)
Research and development, net	$ 21,653	$ 22,695	$ (1,042)
General and administrative	11,754	7,704	4,050
Operating loss	32,853	29,996	2,857
Financial income, net	(549)	(76)	(473)
Loss for the year	$ 32,304	$ 29,920	$ 2,384

Revenues

Revenues for the year ended December 31, 2022 were $0.7 million, compared to $0.8 million for the year ended in 2021, a decrease of $0.1 million. The decrease is due to the winding down of the revenue recognized from the Nanocarrier license agreement.

Cost of revenues for the year ended December 31, 2022 were $0.1 million compared to $0.4 million for the year ended in 2021. The cost of revenues is attributed to the labor costs and other expenses related to the performance obligations that were delivered during the period. Cost of revenues decreased due to the reduction of labor costs associated with the Nanocarrier license agreement.

Research and development expenses, net

Research and development expenses are presented net of grants. Research and development expenses, net, for the year ended December 31, 2022 were $21.7 million, compared to $22.7 million for the year ended December 31, 2021, a decrease of $1.0 million.

The decrease in research and development expenses, net, in 2022 was mainly related to the increase in labor severance costs due to our August 2022 reduction in workforce of approximately $0.6 million, offset by a decrease in VB-601 development of about $1.0 million and $0.7 million in funding by EIC accelerator received in 2022 compared to 2021.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2021 were $11.8 million, compared to $7.7 million for the year ended December 31, 2021, an increase of $4.1 million.

This increase in 2022 is mainly attributed to share-based compensation expense and U.S. operational and professional costs incurred in 2022 compared to 2021 as we established our U.S. subsidiary in September 2021, in addition to an increase in legal costs and labor severance obligations for terminated employees due to the reduction in workforce and strategic process.

Financial income, net

Financial income, net for the year ended December 31, 2022 was $0.5 million, compared to $0.1 million for the year ended December 31, 2021, an increase of $0.4 million in income. The increase in 2022 in mainly due to favorable exchange rates compared to 2021.

Liquidity, Capital Resources, and Financial Requirements

Since our inception and through December 31, 2022, we have raised an aggregate of $327.0 million to fund our operations, including $29.4 million from IIA grants and $1.1 million from the EIC. Our primary uses of cash have historically been to fund working capital requirements and research and development, and we expect these will continue to represent our primary uses of cash subject to our strategic process. Subject to the outcome of this process, we intend to use our cash resources, together with the proceeds from our previous offerings, to advance clinical programs, working capital, and other general corporate purposes.

During the year ended December 31, 2021, we received $26.4 million in net proceeds from the sale of ordinary shares and pre-funded warrants in an underwritten public offering and an aggregate of $23.1 million in gross proceeds from warrant exercises, sales under our at-the-market facility with Oppenheimer & Co. Inc., or the Oppenheimer ATM, and direct shares sales under the ordinary share purchase agreement.

In February 2022, we terminated the Oppenheimer ATM and entered into the Jefferies ATM pursuant to an Open Market Sale Agreement[SM] with Jefferies LLC or Jefferies, providing for the offer and sale from time to time of our ordinary shares having an aggregate offering price of up to $50.0 million. To date we have not sold any shares under the Jefferies ATM.

In December 2022, we terminated an ordinary share purchase agreement with an institutional investor (pursuant to which we had issued in aggregate year to date 1,400,000 shares for gross proceeds of approximately $3.0 million).

On December 31, 2022, we had cash, cash equivalents, short-term bank deposits and restricted bank deposits of $21.1 million and working capital of $15.4 million. Based on our current cash resources, and successful implementation of our reduction in workforce, we believe our current cash as of December 31, 2022 will be sufficient to fund estimated operating expenses and capital expenditure requirements for at least 12 months from the date of the filing of these financial statements. We undertook a review of our strategic options and any transaction resulting therefrom (such as the Merger and the proposed sale of our rights to lease the Modi'in facility and certain related assets) may impact our projection. Further, our losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of any clinical trials, the receipt of payments under any future collaboration agreements it may enter into, our expenditures on other research and development activities, as well as any strategic options we may pursue. We may seek to raise more capital to pursue additional activities, including through a combination of private and public equity offerings, debt, government grants, strategic collaborations and licensing arrangements. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. We are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of VB-601 and any other product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. In any event, we will require additional capital to obtain regulatory approval for our product candidates. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our ordinary shares. Debt financing, if available, 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 collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams or research program or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or grant rights to develop and market our product candidate that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Year ended December 31,	
	2022	2021
		(in thousands)
Cash used in operating activities	$ (31,594)	$ (24,984)
Cash generated from (used in) investing activities	27,296	(15,489)
Cash provided by financing activities	22	49,109
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (4,276)	$ 8,636

Operating Activities

Cash used in operating activities for the year ended December 31, 2022 was $31.6 million and consisted primarily of a net loss of $32.3 million arising primarily from research and development activities in addition to net working capital of $2.6 million, offset by a $3.3 million in net aggregate non-cash charges.

Cash used in operating activities for the year ended December 31, 2021 was $25.0 million and consisted primarily of a net loss of $29.9 million arising primarily from research and development activities, and partially offset by a $1.7 million in net increase in working capital and an aggregate of $3.2 million in non-cash charges.

Investing Activities

Net cash generated from investing activities was $27.3 million for the year ended December 31, 2022. This was primarily due to $31.1 million maturation of short-term bank deposits, offset by $3.0 million investments in short-term bank deposits.

Net cash used in investing activities was $15.5 million for the year ended December 31, 2021. This was primarily due to $51.1 million of investments in short-term bank deposits, offset by the maturation of $37.1 in short-term bank deposits.

Financing Activities

Net cash provided by financing activities was $0.02 million for the year ended December 31, 2022.

Net cash provided by financing activities was $49.1 million for the year ended December 31, 2021 and was mainly the result of the proceeds from the April underwritten public offering of ordinary shares and pre-funded warrants, as well as the sales of shares pursuant to the Oppenheimer ATM and direct sales under an agreement with an institutional investor.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear beginning on page F-1 of this Annual Report for the year ended December 31, 2022.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We have performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that the material financial and non-financial information required to be disclosed to the SEC is recorded, processed, summarized and reported timely. Based on our evaluation, our management, including the Chief Executive Officer, or CEO, and the Chief Financial Officer, or CFO, has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report are effective. Notwithstanding the foregoing, there can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within our company to disclose material information otherwise required to be set forth in our reports.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) promulgated under the Exchange Act. Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the reliability of financial reporting and the preparation and fair presentation of published financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

Our management, including our CEO and CFO, conducted an evaluation, pursuant to Rule 13a-15(c) promulgated under the Exchange Act, of the effectiveness, as of the end of the period covered by this Annual Report, of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013). Based on the results of this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Changes in Internal Control over Financial Reporting

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 occurred during the fiscal year ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth certain information relating to our executive officers and directors, including their ages as of February 1, 2023.

Name	Age	Position
Executive Officers and Executive Director		
Dror Harats	66	Chief Executive Officer and Director
Sam Backenroth	38	Chief Financial Officer
Non-Executive Directors		
Marc Kozin (1)(3)(4)	61	Chairman and Director
Ruth Alon (2)(3)(4)	71	Director
Shmuel (Muli) Ben Zvi (1)(2)(4)	62	Director
David Hastings (2)(4)	61	Director
Michael Rice (1)(4)	58	Director

(1) Member of the compensation committee.
(2) Member of the audit committee.
(3) Member of the nominating and corporate governance committee.
(4) Independent director under the rules of the Nasdaq Stock Market.

Executive Officers

Dror Harats, M.D., founded our company in 2000 and has served as our chief executive officer since January 2001. He has been a member of our board of directors since January 2001. Prof. Harats received his M.D. from Hadassah Medical School at the Hebrew University of Jerusalem, Israel. Following a residency in internal medicine, he conducted fellowship in pulmonary medicine and post-doctoral work at the University of California, San Francisco. Prof. Harats has also served as a visiting scientist at Syntax Discovery Research. Prof. Harats has more than 30 years of both research in the field of medicine and biotechnology as well as a professional and experienced consultant specializing in the biotechnology & pharmaceutical industry for healthcare organizations and companies. Prof. Harats currently serves on the board of directors of ART Healthcare Ltd, and as a part time chair of the R&D division at the Chaim Sheba Medical Center at Tel Hashomer and as chair of its Institute Review Board. Prof. Harats is also a Professor of Medicine in the Departments of Internal Medicine and Biochemistry at the Sackler Faculty of Medicine of Tel-Aviv University, Israel. We believe Prof. Harats is qualified to serve on our board of directors because of his extensive technical and industry experience, as well as his knowledge of our company.

Sam Backenroth has served as our chief financial officer since October 2021. Prior to joining our company, from 2019 to 2021, Mr. Backenroth was the chief financial officer at NeuBase Therapeutics, a novel genetic medicine platform company focused on rare genetic diseases and oncology. Prior to that, from 2010 to 2019, Mr. Backenroth was the chief financial officer of Ohr Pharmaceutical, where he was instrumental in the company's growth and helped move its lead program from preclinical into late-stage clinical development. He is also a founder of Orphion Therapeutics, a company focused on one-time gene therapy treatments for ocular and central nervous system manifestations of ultra-rare diseases, and DepYmed, Inc., a pharmaceutical company focused on a novel phosphatase inhibition technology platform for rare diseases and cancer. From 2008 to 2010, he was an investment banker with The Benchmark Company LLC, where he raised capital and provided advisory services for biotechnology companies. Mr. Backenroth holds a B.Sc. degree in finance from Touro College.

Non-Executive Directors

Marc Kozin joined our board of directors in November 2020 as vice chairman and was appointed to chairman in July 2021. Mr. Kozin has three decades of industry expertise advising biopharmaceutical, life sciences and medtech companies. He is a member of the board of HCRx (HealthCare Royalty Partners), a leading investment firm in healthcare, providing royalty monetization and senior debt, having been Chair of the strategy advisory board for 7 years. Previously, Mr. Kozin was a career strategy consultant, having served as president of L.E.K. Consulting's North American practice from 1997 to 2012 and as senior advisor from 2012 to 2018. He began his career at L.E.K. in 1987 by helping establish the Boston office and led the development of L.E.K.'s industry-leading life science strategic planning practice. Mr. Kozin has served on more than a dozen boards in a variety of roles and on all committees. He serves as director and serves on the compensation committee of UFP Technologies (Nasdaq: UFPT). Previously, he served as director for Dicerna Pharmaceuticals (Nasdaq: DRNA), prior to its acquisition by Novo Nordisk. He also served on the board of Endocyte (Nasdaq: ECYT), and was also a board member of Dyax (Nasdaq: DYAX), which was acquired by Shire Plc in 2015. He also served on the boards of directors of Brandwise, Inc., Lynx Therapeutics, Inc., Assurance Medical, Inc., Medical Simulation Corporation, Advizex, and CrunchTime! Information Systems. Mr. Kozin has served as director of The Greenlight Fund, a non-profit focused on improving the lives of inner city children in families, since 2017. He was also on the board of governors at New England Medical Center and the board of DukeEngage for several years. Mr. Kozin received a B.S. degree in economics from Duke University in Durham, N.C. and a M.B.A. in finance from The Wharton School of the University of Pennsylvania in Philadelphia. We believe Mr. Kozin is qualified to serve on our board of directors because of his extensive industry and business background.

Ruth Alon has served on our board of directors since March 2010. Ms. Alon is currently the founder and chief executive officer of Medstrada, an advisory and consultancy firm in the healthcare and foodtech sectors. From 1997 to 2016, Ms. Alon has served as a general partner in Pitango Venture Capital, where she headed the life sciences activities and has led several of its portfolio companies to successful acquisitions, among them Disc-O-Tech, Colbar, Ventor and Optonol. Prior to her tenure at Pitango, Ms. Alon held senior analyst positions with Montgomery Securities from 1981 to 1987, Kidder Peabody & Co. from 1987 to 1993 and Genesis Securities, LLC from 1993 to 1996, and managed her own independent consulting business in San Francisco in the medical devices industry from 1995 to 1996. Ms. Alon was the founder and chairperson of Israel Life Science Industry, a not-for-profit organization representing the mutual goals of the then approximately 1000 Israeli life science companies. She was also the co-founder of the Israeli Advanced Technology Industries, or IATI, an umbrella organization of the hi-tech and life sciences industries in Israel, which includes venture capital funds, research and development centers of multinational corporations and others. Ms. Alon is also a board member of Moringa Acquisition Corp (Nasdaq: MACA) and of several privately held companies, including Treos Bio and Phoska Biopharma. She is the chairperson of Brainsgate (privately held). Ms. Alon has a B.A. in Economics from the Hebrew University of Jerusalem, Israel, an M.B.A. from Boston University, and an M.Sc. from the Columbia University School of Physicians and Surgeons. We believe Ms. Alon is qualified to serve on our board of directors because of her extensive business and industry background, as well as her experience as a seasoned investor.

Shmuel (Muli) Ben Zvi, Ph.D., has served on our board of directors since September 2018. Dr. Ben Zvi is currently a board member at Bank Leumi, the largest bank in Israel, and a member of its credit, technology and strategy committees. Dr. Ben Zvi is also a board member of SOL-GEL Technologies (Nasdaq: SLGL) and a member of the audit and compensation committees and a board member and chair of the audit committee of Protalix Biotherapeutics. From 2004 to 2014, Dr. Ben Zvi held various managerial positions at Teva Pharmaceuticals Industries Ltd., dual listed on Nasdaq and the TASE, including as vice president of finance and vice president of strategy. From 2000 to 2004, Dr. Ben Zvi was the financial advisor to the chief of general staff of the Israel Defense Forces and head of the Defense Ministry budget department. Dr. Ben Zvi holds a Ph.D. in economics from Tel-Aviv University, Israel and participated in the Harvard Business School Advanced Management Program (AMP). We believe Dr. Ben Zvi is qualified to serve on our board of directors because of his extensive finance and industry background.

David Hastings has served on our board of directors since January 2018. Mr. Hastings has more than 20 years of finance, accounting and operations experience in the bio-pharmaceutical industry. Mr. Hastings joined Arbutus BioPharma in June 2018 and currently serves as its chief financial officer. Mr. Hastings previously served as the chief financial officer and executive vice president of Incyte Corporation from 2003 until 2014. During this time, Mr. Hastings oversaw all financial aspects as Incyte transitioned from research and development to commercialization, following the launch of Jakafi (ruxolitinib). Mr. Hastings also previously served as vice president, chief financial officer and treasurer of ArQule Inc. During his tenure at ArQule, he played an important role in ArQule's transition into a drug discovery and development organization, and in two strategic acquisitions, including the purchase of Cyclis Pharmaceuticals Inc. Prior to that, Mr. Hastings was with Genzyme Corporation as its vice president and corporate controller, and with Sepracor, Inc. where he was director of finance. Most recently, Mr. Hastings served as the chief financial officer and senior vice president of Unilife Corporation (a medical device company that filed for Chapter 11 bankruptcy in April 2017) from 2015 to 2017 and as its chief accounting officer and treasurer from 2016 to 2017. He is a member of the Board Director of SCYNEXIS, Inc. (Nasdaq: SCYX) and chairs their Audit Committee. We believe Mr. Hastings is qualified to serve on our board of directors because of his extensive financial and business background.

Michael Rice joined our board in July 2021. Mr. Rice has deep experience in portfolio management, investment banking, and capital markets. Mr. Rice is a founding partner of LifeSci Advisors LLC, a life sciences investor relations consultancy, since 2010 and of LifeSci Capital LLC, a research-driven investment bank, since 2013. Previously, Mr. Rice was the co-head of Health Care Investment Banking at Canaccord Adams, where he was involved in debt and equity financing. Mr. Rice was also a managing director at Think Equity Partners, where he was responsible for managing Healthcare Capital Markets, which included structuring and executing numerous transactions. Prior to that, he served as a managing director at Bank of America serving large hedge funds and private equity healthcare funds while working closely with Investment Banking. Previously, he was a managing director at JP Morgan/Hambrecht & Quist. Mr. Rice graduated from the University of Maryland with a degree in Economics and currently sits on the board of 9 Meters Biopharma Inc. (Nasdaq: NMTR) and Navidea Biopharmaceuticals, Inc. (NYSE: NAVB). We believe Mr. Rice is qualified to serve on our board of directors because of his extensive banking and industry background.

Board Diversity Matrix

We have no formal policy regarding board diversity. Our board of directors believes that each director should have a basic understanding of our principal operational and financial objectives and plans and strategies, our results of operations and financial condition and relative standing in relation to our competitors. We take into consideration the overall composition and diversity of the board and areas of expertise that director nominees may be able to offer, including business experience, knowledge, abilities and customer relationships. Generally, we will strive to assemble a board that brings to us a variety of perspectives and skills derived from business and professional experience as we may deem are in our and our shareholders' best interests. In doing so, we will also consider candidates with appropriate non-business backgrounds. Pursuant to Rules 5605(f) and 5606 of the Nasdaq Listing Rules, we have made our board diversity matrix available on our website at www.vblrx.com in the "Corporate Governance" section under the "Investor Relations" tab.

In addition to the information presented above regarding each of the nominees and continuing directors' specific experience, qualifications, attributes and skills that our board of directors and our nominating and corporate governance committee considered in determining that he or she should serve as a director, we also believe that each of our directors has demonstrated business acumen, integrity and an ability to exercise sound judgment, as well as a commitment of service to our company and our board of directors.

Audit Committee

Under the Companies Law, we are required to appoint an audit committee. The audit committee must be comprised of at least three directors, including all of the external directors, one of whom must serve as chairman of the committee. In accordance with the exemption available to certain Israeli public companies, whose shares are traded on Nasdaq, we chose as of November 7, 2016 and for as long the required conditions precedent are met and unless otherwise decided by our board of directors, not to follow the requirements of Companies Law with regard to the composition of the audit committee, and instead, will follow the Nasdaq rules applicable to U.S. domestic companies with respect to the appointment and composition of the audit committee.

Under the Nasdaq listing requirements, we are required to maintain an audit committee consisting of at least three independent directors, all of whom are financially literate and at least one of whom has accounting or related financial management expertise. Our audit committee consists of David Hastings, Ruth Alon and Shmuel (Muli) Ben Zvi and is chaired by Mr. Hastings. Mr. Hastings and Dr. Ben Zvi are the audit committee financial experts as defined by SEC rules and all of the members of our audit committee have the requisite financial literacy as defined by the Nasdaq Stock Market rules. All the members of our audit committee are "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act and under the listing standards of Nasdaq.

Audit Committee Financial Expert

All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq corporate governance rules. Our board of directors has determined that David Hastings and Shmuel (Muli) Ben Zvi are the audit committee financial experts as defined by the SEC rules, has the requisite financial experience and is independent as defined by the Nasdaq corporate governance rules.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics applicable to all of our directors and employees, including our CEO, CFO, controller or principal accounting officer, or other persons performing similar functions. The full text of the Code of Business Conduct and Ethics is posted on our website at *https://ir.vblrx.com/corporate-governance*. Information contained on, or that can be accessed through, our website does not constitute a part of this Form 10-K and is not incorporated by reference herein. If we make any substantive amendments to, or grant any waivers from, our Code of Business Conduct and Ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Item 11. EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2022 are:

- Dror Harats, M.D., our Chief Executive Officer; and
- Sam Backenroth, our Chief Financial Officer.

2022 Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers for the years indicated. We did not provide any "nonqualified deferred compensation" in either period so we have eliminated that column from the table below.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Stock Awards ($)(2)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)(3)	All Other Compensation ($)(4)	Total ($)
Dror Harats, M.D.	2022	357,462	-	168,000	275,291	-	86,871	887,624
Chief Executive(5) Officer and Director	2021	349,190	-	-	457,249	219,244	79,759	1,105,442
Sam Backenroth(6)	2022	410,000	-	168,000	91,082	-		669,082
Chief Financial Officer	2021	100,792	100,000	-	681,188	41,000		922,980

(1) For Mr. Backenroth, 2021 reflects a $100,000 sign on bonus.

(2) Amounts represent the aggregate grant date fair value of the stock and option awards granted to our named executive officers during the corresponding fiscal year, computed in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 9 to our annual audited consolidated financial statements included elsewhere herein. This amount does not correspond to the actual value that may be recognized by the named executive officer upon exercise of the applicable award or sale of the underlying ordinary shares.

(3) Amounts represent the annual bonuses paid with respect to achievement of pre-defined corporate and, if applicable, individual performance, objectives for the corresponding fiscal year. Performance bonuses for 2022, if any, have not yet been determined by the compensation committee.

(4) For Prof. Harats, 2022 includes $45,512 for a car provided by us, $36,802 for tax gross up for the car, $375 for phone services provided to our executives, as well as $4,182 for security services. In 2021, includes $36,778 for a car provided by us, $38,245 for tax gross up for the car, $390 for phone services provided to our executives, as well as $4,346 for security services.

(5) Prof. Harats receives an aggregate of $30,000 per month (NIS 100,000), which is allocated between his employment agreement and consulting agreement.

(6) Mr. Backenroth joined our company as Chief Financial Officer in October 2021. Accordingly, the amounts reported in the Salary and Non-Equity Incentive Plan columns, above, have been prorated to reflect Mr. Backenroth's shortened year of service.

Narrative to 2022 Summary Compensation Table

Our board of directors and compensation committee review compensation annually for our executive officers. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our shareholders, and a long-term commitment to our company. We target a general competitive position, based on independent third-party benchmark analytics to inform the mix of compensation of base salary, bonus or long-term incentives.

Our compensation committee is authorized to retain the services of one or more executive compensation advisors, as it sees fit, in connection with the establishment of our executive compensation programs and related policies. In fiscal year 2022, the compensation committee utilized the Radford database to provide it with market information, analysis and other advice relating to executive compensation on an ongoing basis. The compensation committee utilized this information to, among other things, help us determine overall compensation for our executive officers, as well as to assess each separate element of compensation. The goal was to ensure that the compensation we offer to our executive officers, individually as well as in the aggregate, is competitive and aligned with our business and executive talent requirements. We do not believe our access if this information creates any conflict of interest because Radford performs no other work for our company besides advising the compensation committee.

Our compensation committee is responsible for determining the compensation for all executive officers. Based on its discretion, taking into account the factors noted above, the compensation committee sets the compensation for each executive officer, including for the Chief Executive Officer, without the Chief Executive Officer present.

Base salaries

Our named executive officers each receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Base salaries are reviewed annually, typically in connection with our annual performance review process, approved by our board of directors or the compensation committee, and may be adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, and experience.

For fiscal year 2022, the annual base salary for each of Prof. Harats and Mr. Backenroth were NIS 1,200,000 ($357,462) and $410,000, respectively. For Prof. Harats, his monthly compensation is allocated as amongst his employment agreement (20%) and consulting agreement (80%).

We pay cash bonuses to reward our executives for their performance over the fiscal year, based on the achievement of certain corporate performance goals and, if applicable, individual performance goals. We believe such bonuses properly incentivize our named executive officers and allow us to remain competitive within the marketplace. The target annual bonuses for Prof. Harats and Mr. Backenroth for the fiscal year ended December 31, 2022, were 50% and 40% of annual base salary, respectively. Considering the outcome of the OVAL study and our ongoing strategic process, the compensation committee has not yet determined if there will be any bonuses awarded for service in 2022, and if there is, what these reduced amounts would be.

Equity Compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our shareholders. In addition, we believe that equity grants promote executive retention because they incentivize our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors or our compensation committee periodically review the equity incentive compensation of our named executive officers and may grant equity incentive awards to them from time to time. During fiscal year 2022, we granted both options to purchase ordinary shares and RSUs to Prof. Harats and Mr. Backenroth, as described in more detail in the "Outstanding Equity Awards at 2022 Fiscal Year End" table.

Perquisites

We generally do not provide perquisites to our executives, other than reimbursements for certain travel and relocation expenses. However, we do provide our executive officers with cell phone plans, and for Prof. Harats, we also provide a company car (along with tax gross up on the value), as well as a security detail when in Israel.

401(k) Plan

We currently maintain a 401(k) retirement savings plan for our U.S. employees who satisfy certain eligibility requirements. Currently, our sole U.S. employee is Sam Backenroth and he is eligible to participate in the 401(k) plan on the same terms as other U.S. full-time employees, if any. Our 401(k) plan is intended to qualify for favorable tax treatment under Section 401(a) of the Internal Revenue Code of 1986, as amended, or the Code, and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. We believe that providing a vehicle for tax-deferred retirement savings though our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies. We do not provide matching contributions.

Executive Employment and Other Compensation Arrangements

Prof. Dror Harats, M.D.

On January 20, 2022, we entered into a restated executive employment agreement and consulting agreement (through Grand H Services Ltd.) with Prof. Harats pursuant to which he provides services as our Chief Executive Officer. His agreements sets forth his gross monthly salary of NIS 100,000 (approx. $30,000) and fringe benefits, which is allocated 20% to his employment agreement and 80% to his consulting agreement, at his discretion. In addition, we provide Prof. Harats with a company car for his use and a gross-up for any taxes due in connection with Prof. Harats' automobile and an annual bonus target equal to 50% of the annual compensation payable to be paid according to milestones to be determined by our board of directors, and in accordance with our Compensation Policy. Prof. Harats is also subject to confidentiality, noncompetition and nonsolicitation covenants under his employment agreement and is eligible for equity awards under our equity compensation plans.

In August 2022, the Compensation Committee awarded Prof. Harats a grant of 700,000 RSUs as retention to remain employed with us through the strategic process. The award vests 75% at March 31, 2023, with the reminder on the two year anniversary of the grant, subject to acceleration upon change of control (such as completion of the Merger).

We can terminate Prof. Harats' employment agreement (as can he) for any reason by giving nine months prior written notice of termination. However, in the event that Prof. Harats' employment is terminated other than for "cause" (as defined therein) or if Prof. Harats resigns for "good reason" (as defined therein), Prof. Harats will be entitled to receive an aggregate of 15 months of salary and benefits continuation under his agreements.

Mr. Sam Backenroth

On October 4, 2021, we entered into an offer letter with Mr. Backenroth for his services as our Chief Financial Officer. Pursuant to his offer letter, Mr. Backenroth's initial annual salary was $410,000, with an annual performance target bonus equal to 40% of his base salary. Mr. Backenroth's employment is on an "at will" basis. Additionally, pursuant to his offer letter, we granted Mr. Backenroth an option to purchase 305,537 ordinary shares under the 2014 Plan and Mr. Backenroth is eligible for additional grants under our equity compensation plans from time to time as determined by our compensation committee. Mr. Backenroth also received a $100,000 one-time signing bonus paid upon commencement of his employment.

In August 2022, the Compensation Committee awarded Mr. Backenroth a grant of 700,000 RSUs as retention to remain employed with us through the strategic process. The award vested 75% at March 31, 2023, with the reminder on the two year anniversary of the grant, subject to acceleration upon change of control (such as completion of the Merger).

Mr. Backenroth's employment with us is at-will, meaning either we or Mr. Backenroth could terminate the employment relationship at any time, with or without cause. If Mr. Backenroth is terminated by us without cause or Mr. Backenroth resigns for good reason (defined generally as a reduction in his salary amongst similarly-situated employees, relocation, or a material diminution in title, duties or responsibilities) regardless of whether such termination or resignation was a result of a change of control, then, subject to execution and delivery of a general release of all claims, his then outstanding, unvested options, if any, will vest and be exercisable as to all of the covered shares. We will also be obligated to pay Mr. Backenroth (1) severance pay at a rate equal to one hundred percent (100%) of his base salary for a period of twelve (12) months from the date of termination, and (2) reimbursement of 12 months of health benefits (COBRA subsidization) in accordance with our standard expense reimbursement procedures.

Mr. Backenroth also entered into our standard indemnification agreement, confidentiality and invention assignment agreement, and non-competition agreement.

Outstanding Equity Awards at Fiscal 2022 Year-End

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of fiscal year 2022:

	OPTION AWARDS (1)				STOCK AWARDS	
NAME	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($) (2)
Dror Harats	—	—	—	—	700,000(3)	$84,000
	-	160,000(4)	2.12	01/02/2042	—	—
	60,000	180,000(5)	2.31	12/07/2041	—	—
	120,000	120,000(5)	1.22	12/08/2041	—	—
	180,000	60,000(5)	1.22	12/19/2039	—	—
	240,000	—	1.22	12/17/2038	—	—
	80,000	—	5.99	10/24/2037	—	—
	75,000	—	5.08	11/07/2036	—	—
	45,000	—	3.32	09/30/2033	—	—
	45,000	—	3.32	12/17/2032	—	—
	30,002	—	3.32	12/20/2031		
	59,999	—	3.32	08/10/2031		
	223,029	—	2.47	06/16/2028		
	148,470	—	2.47	03/27/2028		
Sam Backenroth	—	—	—	—	700,000(3)	$84,000
	-	52,937(4)	2.12	01/02/2042	—	—
	19,851	59,554(5)	2.31	12/07/2041	—	—
	76,875	230,625(5)	2.22	10/04/2041	—	—

(1) Each of the outstanding equity awards in the table above granted prior to our initial public offering was granted pursuant to our Employee Share Ownership and Option Plan (2000), or the 2000 Plan, or our Employee Share Ownership and Option Plan (2011), or the 2011 Plan. Each of the outstanding equity awards in the table above granted following our initial public offering was granted pursuant to our Employee Share Ownership and Option Plan (2014), or the 2014 Plan.

(2) Amounts are equal to $0.12, the closing price of our ordinary shares on December 30, 2022, the last business day of 2022, times the number of unvested RSUs.

(3) The RSUs vest as follows: 75% of the RSUs shall vest on March 31, 2023, with the remaining 25% vesting on August 9, 2024 (or, if earlier, upon completion of the Merger).

(4) The shares vest over three years commencing on the grant date such that 1/3 vest on the first anniversary of the date of grant and then quarterly thereafter for two years, such that they are vested in full on the three-year anniversary of the grant date.

(5) The shares vest over four years commencing on the grant date such that 25% vest on the first anniversary of the date of grant and quarterly thereafter for three years such that they are vested in full on the four-year anniversary of the grant date.

2022 Director Compensation Table

The following table presents the total compensation for each person who served as a non-employee member of our board of directors and received compensation for such service during fiscal year 2022. Other than as set forth in the table below, we did not pay any compensation, make any additional equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in fiscal year 2022. Directors who also serve as employees received no additional compensation for their service as directors. During fiscal year 2022, Dror Harats, M.D., our Chief Executive Officer, was a member of our board of directors, as well as an employee, and received no additional compensation for his services as a director. See "—2022 Summary Compensation Table" above for more information about his compensation in fiscal year 2022. Our non-employee directors did not receive any stock awards, non-equity incentive plan compensation, non-qualified deferred compensation or any other compensation. Accordingly, we have eliminated those columns from the table below.

NAME	FEES EARNED OR PAID IN CASH ($)	OPTION AWARDS ($) (1)	TOTAL ($)
Ruth Alon	53,751	40,497	94,248
Shmuel (Muli) Ben Zvi	56,387	40,497	96,884
Ron Cohen(2)	25,083	40,497	65,680
Alison Finger(2)	25,083	40,497	65,680
David Hastings	60,801	40,497	101,298
Marc Kozin	115,000	90,665	205,665
Bennett Shapiro(2)	75,000	40,497	115,497
Michael Rice	56,000	40,497	96,497

(1) Amounts represent the aggregate grant date fair value of option awards granted to our directors during our fiscal year ended December 31, 2022, computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 9 to our annual audited consolidated financial statements included elsewhere herein. This amount does not correspond to the actual value that may be recognized by the director upon exercise of the applicable award or sale of the underlying shares of stock. Except as noted below, none of our directors held options to purchase ordinary shares or any other stock awards as of December 31, 2022.

(2) Resigned from our board of directors in August 2022.

NAME	AGGREGATE NUMBER OF SHARES SUBJECT TO STOCK OPTIONS HELD AS OF DECEMBER 31, 2022 (#)
Marc Kozin	432,343
Ruth Alon	221,113
Shmuel (Muli) Ben Zvi	194,113
Ron Cohen	-
Alison Finger	-
David Hastings	224,113
Bennett Shapiro	-
Michael Rice	146,113

Non-Employee Director Compensation Policy

At our annual general meeting held on October 19, 2021, our shareholders approved the terms of the Non-Employee Directors New Compensation Scheme, effective as of the date of the said annual general meeting, which provides for the following:

Board of Directors:		
Members	$	35,000
Annual retainer for non-executive chair	$	100,000
Audit Committee:		
Members (other than chair)	$	7,500
Retainer for chair	$	15,000
Compensation Committee:		
Members (other than chair)	$	6,000
Retainer for chair	$	12,000
Nominating and Corporate Governance Committee:		
Members (other than chair)	$	4,000
Retainer for chair	$	8,000

In addition, the non-employee director compensation policy provides that, upon initial election to our board of directors, each non-employee director will be granted an equity grant equal to 0.1% of our capital on a fully diluted basis as of the date of grant. The initial grant will vest upon and in the manner approved by the compensation committee and the board of directors, but not less than two years until full vesting. Furthermore, each non-employee director who continues as a non-employee director will be granted an equity grant equal to 0.067% of our share capital on a fully diluted basis as of the date of grant. The annual grant will vest upon and in the manner approved by the compensation committee and the board of directors, but not less than two years until full vesting. Such awards are subject to full accelerated vesting upon the sale of our company (such as the proposed Merger).

We also reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of our board of directors or any committee thereof. employee directors additional compensation for their service as a director.

Compensation Risk Assessment

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking. This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to remain focused on both short-term and long-term strategic goals, in particular in connection with our pay-for-performance compensation philosophy. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on us.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information with respect to the beneficial ownership of our ordinary shares, as of March 10, 2023, by:

- each person or entity known by us to own beneficially more than 5% of our outstanding ordinary shares;
- each of our executive officers and directors individually; and
- all of our executive officers and directors as a group.

The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power, or the right to receive the economic benefit of ownership. For purposes of the table below, we deem ordinary shares issuable pursuant to options that are currently exercisable or exercisable within 60 days of March 10, 2023 to be outstanding and to be beneficially owned by the person holding the options for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. The percentage of ordinary shares beneficially owned is based on 69,750,117 ordinary shares outstanding as of March 10, 2023.

Except as contemplated by the Merger, we do not know of any arrangements, including any pledge by any person of our securities, the operation of which may at a subsequent date result in a change of control of our company.

Information with respect to beneficial ownership by 5% shareholders has been based on information filed with the SEC pursuant to Section 13(d) or Section 13(g) of the Exchange Act, as well as our records and other information provided to the company. Except as otherwise set forth in the footnotes to the following table, the address of each beneficial owner is c/o Vascular Biogenics Ltd., 8 HaSatat St., Modi'in, Israel 7178106,

Name	Number of Ordinary Shares Beneficially Owned	Percentage of Ownership
>5% Shareholders		
Thai Lee [(1)]	7,400,000	9.6%
Aurum Ventures M.K.I. Ltd [(2)]	6,839,059	9.8%
David M. Slager [(3)]	4,203,082	6.0%
Executive Officers and Directors		
Dror Harats [(4)]	3,082,142	4.3%
Ruth Alon [(5)]	171,758	*
Shmuel (Muli) Ben Zvi [(6)]	204,758	*
David Hastings [(7)]	174,758	*
Marc Kozin [(8)]	296,714	*
Michael Rice [(9)]	69,571	*
Sam Backenroth† [(10)]	687,184	*
All directors and executive officers as a group (7 individuals total) [(11)]	4,686,885	6.4%

* Less than 1%

† Address is 1 Blue Hill Plaza, Suite 1509, Pearl River, NY 10965.

(1) Consists of 7,400,000 pre-funded warrants to purchase ordinary shares exercisable as of March 10, 2023. Such pre-funded warrants are only exercisable to the extent that Thai Lee, together with her affiliates, would beneficially own no more than 19.99% of the outstanding ordinary shares after giving effect to such exercise, or the Lee Beneficial Ownership Limitation. The principal business address of Ms. Lee is 70 Rainey Street, Austin, TX 78701.

(2) Consists of 6,839,059 ordinary shares held directly by Aurum Ventures M.K.I. Ltd. Voting and investment power over such shares are vested with Mr. Morris Kahn, who controls Aurum Ventures M.K.I. Ltd. As such, Mr. Kahn may be deemed to have beneficial ownership over our shares held by Aurum Ventures M.K.I. Ltd. The address of Aurum Ventures M.K.I. Ltd. is 16 Abba Hillel Silver Rd., Ramat Gan, 5250608, Israel.

(3) Consists of (i) 1,812,913 ordinary shares held by Regals Capital Management LP, (ii) 1,740,169 ordinary shares held directly by David M. Slager and (iii) 650,000 pre-funded warrants held by Regals Fund LP. Mr. Slager may be deemed to have beneficial ownership over our shares and warrants held by Regals Capital Management LP and Regals Fund LP. The address of Regals Capital Management LP and Regals Fund LP is 152 West 57th Street, 9th Floor, New York, NY 10019.

(4) Consists of (a) 1,138,975 ordinary shares held by or for Prof. Harats; (b) 1,418,167 shares underlying options exercisable within 60 days of February 15, 2023; and (c) 525,000 RSU's vesting within 60 days of March 10, 2023.

(5) Consists of 171,758 shares underlying options exercisable within 60 days of February 15, 2023.

(6) Consists of (a) 60,000 ordinary shares held by or for Dr. Ben Zvi; and (b) 144,758 shares underlying options exercisable within 60 days of March 10, 2023.

(7) Consists of 174,758 shares underlying options exercisable within 60 days of March 10, 2023.

(8) Consists of (a) 39,000 ordinary shares held by the Marc D. Kozin Irrevocable Trust; and (b) 257,714 shares underlying options exercisable within 60 days of March 10, 2023.

(9) Consists of 69,571 shares underlying options exercisable within 60 days of March 10, 2023.

(10) Consists of (a) 162,184 shares underlying options exercisable within 60 days of February 15, 2023; and (b) 525,000 RSU's vesting within 60 days of March 10, 2023.

(11) Consists of (a) 1,237,975 ordinary shares; (b) 2,398,910 shares issuable to our current directors and executive officers pursuant to outstanding options to purchase our ordinary shares which are exercisable within 60 days of March 10, 2023; and (c) 1,050,000 shares to be issued pursuant to RSUs vesting within 60 days of March 10, 2023.

Equity Compensation Plan Information

The following table provides information as of December 31, 2022, with respect to the ordinary shares that may be issued under our existing equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (#) (a)	Weighted average exercise price of outstanding options, warrants and rights ($) (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities in column (a)) (#) (c)
Equity compensation plans approved by security holders(1)	8,518,617(3)	2.08(3)	3,867,230(4)
Equity compensation plans not approved by security holders(2)	-	-	2,000,000(5)
Total	8,518,617	2.08	5,867,230

(1) Includes the following plans: the 2000 Plan, the 2011 Plan, and the 2014 Plan.
(2) Reflects the Vascular Biogenics Ltd. Inducement Plan (2022), or the Inducement Plan.
(3) Consists of 6,818,617 shares issuable upon the exercise of outstanding options under the 2000 Plan, the 2011 Plan, and the 2014 Plan and 1,700,000 shares issuable upon the vesting of RSUs.
(4) As of December 31, 2022, a total of 3,867,230 ordinary shares have been reserved for issuance pursuant to the 2014 Plan, which number excludes the shares that were added to the plan as a result of the automatic annual increase on January 1, 2023 (which has yet to be ratified by our board of directors as required under Israeli law). The 2014 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by 4% of the outstanding number of ordinary shares on the immediately preceding December 31. This number will be subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. The ordinary shares underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated, other than by exercise, under the 2014 Plan, the 2011 Plan and the 2000 Plan will be added back to the ordinary shares available for issuance under the 2014 Plan. The Company no longer makes grants under the 2000 Plan and 2011 Plan.
(5) As of December 31, 2022, no ordinary shares of have been reserved for issuance pursuant to outstanding awards under the Inducement Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Certain Relationships and Transactions

Other than the compensation agreements and other arrangements described under “Executive Compensation” and “Non-Employee Director Compensation” in this Form 10-K and the transactions described below, since January 1, 2021, there has not been and there is not currently proposed, any transaction or series of similar transactions to which we were, or will be, a party in which the amount involved exceeded, or will exceed, $120,000 (or, if less, 1% of the average of our total assets amounts at December 31, 2021 and 2022) and in which any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of the foregoing persons, had, or will have, a direct or indirect material interest.

In December 2021, we entered into a master service agreement with LifeSci Advisors for investor relations services. Michael Rice, VBL independent Director, is a principal in the firm. The Audit Committee reviewed and approved the arrangement for a monthly retainer of $20,000. In August 2022, following the results of the OVAL study, the monthly retainer was reduced to $5,000 per month.

On July 7, 2022, our shareholders approved the compensation policy for our directors and other officers of the Company. See "Item 11. Executive Compensation—Non-Employee Director Compensation Policy" for additional discussion on our compensation policy.

Approval of Related Party Transactions Under Israeli Law

Fiduciary Duties of Directors and Executive Officers

The Companies Law codifies the fiduciary duties that office holders owe to a company. Each person listed in the table under "Management-Executive Officers, Senior Management and Directors" and management members of at least a VP level are considered an office holder under the Companies Law.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of loyalty requires that an office holder act in good faith and in the best interests of the company.

The duty of care includes a duty to use reasonable means 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 includes a duty to:

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

Disclosure of Personal Interests of an Office Holder and Approval of Certain Transactions

The Companies Law requires that an office holder promptly disclose to the company any personal interest that he or she may be aware of and all related material information or documents concerning 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 a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered as an extraordinary transaction.

A "personal interest" is defined under the Companies Law to include a personal interest of any person in an act or transaction of a company, including the personal interest of such person's relative or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, but excluding a personal interest stemming from one's ownership of shares in the company.

A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the personal interest of the office holder with respect to his or her vote on behalf of a person for whom he or she holds a proxy even if such shareholder has no personal interest in 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 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.

If it is determined that an office holder has a personal interest in a transaction, approval by the board of directors is required for the transaction, unless the company's articles of association provide for a different method of approval. Further, so long as an office holder has disclosed his or her personal interest in a transaction, the board of directors may 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. An extraordinary transaction in which an office holder has a personal interest requires approval first by the company's audit committee and subsequently by the board of directors. The compensation of, or an undertaking to indemnify or insure, an office holder who is not a director requires approval first by the company's compensation committee, then by the company's board of directors, and, if such compensation arrangement or an undertaking to indemnify or insure is inconsistent with the company's stated compensation policy or if the office holder is the chief executive officer (apart from a number of specific exceptions), then such arrangement is subject to a special majority approval. Arrangements regarding the compensation, indemnification or insurance of a director require the approval of the compensation committee, board of directors and shareholders by ordinary majority, in that order, and under certain circumstances, a special majority approval. If shareholders of a company do not approve the compensation terms of office holders, other than directors, but including the chief executive officer, the compensation committee and board of directors may override the shareholders' decision, subject to certain conditions.

Generally, a person who has a personal interest in a matter which is considered at a meeting of the board of directors or the audit committee may not be present at such a meeting or vote on that matter unless the chairman of the relevant committee or board of directors (as applicable) determines that he or she should be present in order to present the transaction that is subject to approval. If a majority of the members of the audit committee or the board of directors (as applicable) has a personal interest in the approval of a transaction, then all directors may participate in discussions of the audit committee or the board of directors (as applicable) on such transaction and the voting on approval thereof, but shareholder approval is also required for such transaction.

Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions

Pursuant to Israeli law, the disclosure requirements regarding personal interests that apply to directors and executive officers also apply to a controlling shareholder of a public company. In the context of a transaction involving a shareholder of the company, a controlling shareholder also includes a shareholder who holds 25% or more of the voting rights in the company if no other shareholder holds more than 50% of the voting rights in the company. For this purpose, the holdings of all shareholders who have a personal interest in the same transaction will be aggregated. The approval of the audit committee, the board of directors and a special majority, in that order, is required for (a) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, (b) the engagement with a controlling shareholder or his or her relative, directly or indirectly, for the provision of services to the company, (c) the terms of engagement and compensation of a controlling shareholder or his or her relative who is not an office holder or (d) the employment of a controlling shareholder or his or her relative by the company, other than as an office holder.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval is required once every three years, unless, with respect to certain transactions, the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Arrangements regarding the compensation, indemnification or insurance of a controlling shareholder in his or her capacity as an office holder require the approval of the compensation committee, board of directors and shareholders by a special majority and the terms thereof may not be inconsistent with the company's stated compensation policy.

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors, that would otherwise require approval of a company's shareholders may be exempt from shareholder approval upon certain determinations of the audit committee and board of directors. Under these regulations, a shareholder holding at least 1% of the issued share capital of the company may require, within 14 days of the publication of such determinations, that despite such determinations by the audit committee and the board of directors, such transaction will require shareholder approval under the same majority requirements that would otherwise apply to such transactions.

Director Independence

Our ordinary shares are listed on The Nasdaq Capital Market. Under the Nasdaq listing rules, independent directors must comprise a majority of a listed company's board of directors within twelve months from the date of listing. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under Nasdaq listing rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In March 2022, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that all members of the board of directors, except Dror Harats, M.D., are independent directors, including for purposes of Nasdaq and the SEC rules. In making that determination, our board of directors considered the relationships that each director has with us and all other facts and circumstances the board of directors deemed relevant in determining independence, including the potential deemed beneficial ownership of our capital stock by each director and respective affiliations, including non-employee directors that are affiliated with certain of our major shareholders. We expect that the composition and functioning of our board of directors and each of our committees will continue to comply with all applicable requirements of Nasdaq and the rules and regulations of the SEC. There are no family relationships among any of our directors or executive officers. Dror Harats, M.D., is not an independent director under these rules because he is currently employed as the chief executive officer and president of our Company.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Audit fees (1)	$ 303	$ 330
Tax fees (2)	5	5
All other fees (3)	1	-
Total fees	$ 309	$ 335

(1) Audit fees consist of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide, including work regarding the public listing or offerings during 2021 and 2022.

(2) Tax fees consist of tax compliance, planning, and advice.

(3) All other fees consist of a disclosure checklist license.

Our board of directors reviews and pre-approves all audit services and permitted non-audit services (including the fees and other terms) to be provided by our independent auditors pursuant to pre-approval policies and procedures established by the audit committee, which are detailed as to the particular service and the audit committee is informed of each service. The pre-approval policies and procedures do not delegate audit committee responsibilities under the Securities Exchange Act of 1934 to management.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(1) For a list of the consolidated financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item 15 by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the financial statements or the notes thereto.

(3) Exhibits:

Exhibit No.	Description
2.1+	Agreement and Plan of Merger, dated as of February 22, 2023, by and among Vascular Biogenics Ltd., Vibrant Merger Sub, Inc., and Notable Labs, Inc. (incorporated by reference to Exhibit 2.1 to the Form 8-K filed with the Securities and Exchange Commission on February 23, 2023).
2.2*+	Asset Purchase Agreement, dated as of February 15, 2023, by and between the Registrant and Aleph Farms Ltd.
3.1*	Articles of Association of the Registrant, as currently in effect.
3.2*	Memorandum of Association of the Registrant, as currently in effect.
4.1*	Description of Securities.
10.1#	Employee Ownership and Share Option Plan (2011) of the Registrant, and form of agreement thereunder (incorporated by reference to Exhibit 10.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on June 6, 2014).
10.2#	Employee Share Ownership and Option Plan (2014) of the Registrant, and form of Capital Gains Option Agreement thereunder (incorporated by reference to Exhibit 10.17 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on June 25, 2014).
10.3#	Vascular Biogenics Ltd. Inducement Plan (2022) of the Registrant and form of award agreements thereunder (incorporated by reference to Exhibit 99.1 of the Current Report on Form 6-K filed with the Securities and Exchange Commission on February 15, 2022).
10.4#	Form of Release and Indemnification Agreement to be entered into between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.2 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on June 25, 2014).
10.5*#	Restated Executive Employment Agreement between the Registrant and Dror Harats, dated January 20, 2022.
10.6*#	Restated Consulting and Services Agreement between the Registrant and Grand H Services Ltd., dated January 20, 2022, as amended on August 23, 2022.
10.7*#	Employment Offer Letter between the Registrant and Sam Backenroth, dated October 4, 2021.
21.1*	List of Subsidiaries of the Registrant.
23.1*	Consent of Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, Independent Registered Public Accounting Firm.
24.1	Power of attorney (included on signature page hereto)
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a).
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a).
32.1*¥	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File.

Management compensatory plan or arrangement.
+ Schedules have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. We agree to furnish supplementally a copy of any omitted schedule to the SEC upon its request; provided, however, that we may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any schedule so furnished.
* Filed herewith
¥ The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Form 10-K and is not deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

Item 16. FORM 10-K SUMMARY.

Not applicable.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the board of directors and shareholders of Vascular Biogenics Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Vascular Biogenics Ltd. and its subsidiary (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of net loss and comprehensive loss, changes in shareholders' equity and cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinions

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

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

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Subsequent Event

As discussed in Note 1 to the consolidated financial statements, the Company entered into a merger agreement with Notable Labs, Inc. ("Notable") whereby Notable's securityholders will own the majority of the Company's outstanding shares upon consummation of the merger. Additionally, as discussed in Note 1, the Company entered into an agreement to sell its rights to lease the manufacturing facility and certain related assets.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. We determined there are no critical audit matters.

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

Tel Aviv, Israel
March 14, 2023
We have served as the Company's auditor since 2001.

Kesselman & Kesselman, Derech Menachem Begin 146 Tel Aviv-Yafo 6492103 Israel,
P.O Box 7187 Tel-Aviv 6107120 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il]

VASCULAR BIOGENICS LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share amounts)

	December 31	
	2022	2021
	U.S. dollars in thousands	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,665	$ 21,986
Restricted cash	360	-
Short-term bank deposits	3,054	31,164
Other current assets	1,070	1,697
Total current assets	22,149	54,847
Non-current assets:		
Restricted bank deposits	$ -	362
Long-term prepaid expenses	-	182
Funds in respect of employee rights upon retirement	368	415
Property, plant and equipment, net	6,601	6,847
Operating lease right-of-use assets	541	2,008
Total non-current assets	7,510	9,814
Total assets	$ 29,659	$ 64,661
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 808	$ 4,331
Other	5,359	4,408
Deferred revenue	-	658
Current maturity of operating leases	564	529
Total current liabilities	6,731	$ 9,926
Non-current liabilities:		
Liability for employee rights upon retirement	477	546
Operating lease liability	-	1,823
Other non-current liability	-	188
Total non-current liabilities	477	2,557
Commitments (Note 8)		
Total liabilities	$ 7,208	$ 12,483
Ordinary shares subject to possible redemption, as of December 31, 2022 and December 31, 2021, zero and 615,366 shares, respectively, at redemption value (Note 9)	-	1,598
Shareholders' equity:		
Ordinary shares, NIS 0.01 par value; Authorized as of December 31, 2022 and 2021, 200,000,000 and 150,000,000 shares, respectively; issued and outstanding as of December 31, 2022 and 2021, 69,750,117 and 68,711,584 shares, respectively (excluding – zero - and 615,366 subject to possible redemption as of December 31, 2022 and December 31, 2021, respectively)	174	171
Additional paid in capital	316,654	309,355
Warrants	-	3,127
Accumulated deficit	(294,377)	(262,073)
Total equity	22,451	50,580
Total liabilities and equity	$ 29,659	$ 64,661

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

VASCULAR BIOGENICS LTD.
CONSOLIDATED STATEMENTS OF NET LOSS AND COMPREHENSIVE LOSS
(U.S. dollars in thousands, except share and per share amounts)

	Year ended December 31	
	2022	**2021**
	U.S. dollars in thousands	
Revenues	$ 658	$ 768
Cost of revenues	(104)	(365)
Gross profit	554	403
Research and development expenses, net	21,653	22,695
General and administrative expenses	11,754	7,704
Operating loss	32,853	29,996
Financial income	(634)	(120)
Financial expenses	85	44
Financial income, net	(549)	(76)
Net loss and comprehensive loss	$ 32,304	$ 29,920
	U.S. dollars	
Loss per ordinary share		
Basic and diluted	$ 0.42	$ 0.45
	Number of shares	
Weighted average ordinary shares outstanding		
Basic and diluted	77,554,740	66,346,506

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

VASCULAR BIOGENICS LTD.
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(U.S. dollars in thousands, except share and per share amounts)

	Number of ordinary shares	Ordinary shares	Additional paid in capital	Warrants	Accumulated deficit	Total equity	Ordinary shares subject to possible redemption	
							Shares	Amount
				U.S. dollars in thousands				
Balance at January 1, 2021	48,187,463	108	252,561	10,401	(232,153)	30,917	-	-
Changes during the year ended December 31, 2021:								
Net loss	-	-	-	-	(29,920)	(29,920)	-	-
Issuance of ordinary shares	28,334	*	-	-				
Issuance of ordinary shares and warrants, net of issuance costs of $2.2 million	8,971,790	27	30,925	-	-	30,952	-	-
Exercised warrants	11,523,997	36	20,974	(4,347)	-	16,663		
Expired warrants	-	-	2,927	(2,927)	-	-	-	-
Issuance of ordinary shares subject to possible redemption	-	-	-	-		--	615,366	$ 1,598
Share-based compensation	-	-	1,968	-	-	1,968	-	-
Balance at December 31, 2021	68,711,584	171	309,355	3,127	(262,073)	50,580	615,366	$ 1,598
Changes during the year ended December 31, 2022:								
Net loss	-	-	-	-	(32,304)	(32,304)	-	-
Expired warrants	-	-	3,127	(3,127)	-	-	-	-
Reclassification of redemption shares into ordinary shares	615,366	2	1,596			1,598	(615,366)	(1,598)
Share-based compensation to employees and service provider	34,258	*	2,555	-	-	2,555	-	-
Employee exercise of stock options	388,909	1	21			22		
Balance at December 31, 2022	69,750,117	$ 174	$ 316,654	$ -	$ (294,377)	$ 22,451	$ -	$ -

*Amount less than $1 thousand

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

VASCULAR BIOGENICS LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31,	
	2022	**2021**
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (32,304)	$ (29,920)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,058	$ 1,256
Interest expense (income)	2	(31)
Net changes in operating leases	(321)	46
Interest expenses on leases	-	(2)
Exchange loss (gain) on cash and cash equivalents and restricted cash	47	(15)
Changes in accrued liability for employee rights upon retirement	(22)	11
Share-based compensation	2,555	1,968
Changes in operating assets and liabilities:		
Decrease (increase) in other current assets and long-term prepaid expenses	809	(219)
Decrease in trade receivables	-	129
Increase (decrease) in accounts payable and accruals:		
Trade	(3,523)	2,371
Other (including other non-current liability)	763	193
Decrease in deferred revenue	(658)	(771)
Net cash used in operating activities	$ (31,594)	$ (24,984)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(812)	(1,465)
Investment in short-term bank deposits	(3,000)	(51,109)
Maturity of short-term bank deposits	31,108	37,085
Net cash provided by (used in) investing activities	$ 27,296	$ (15,489)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares and warrants	$ 22	$ 33,155
Issuance costs	-	(2,202)
Proceeds from issuance of ordinary shares subject to possible redemption	-	1,598
Proceeds from exercised warrants	-	16,662
Finance lease payments	-	(104)
Net cash provided by (used in) financing activities	$ 22	$ 49,109
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	$ (4,276)	$ 8,636
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF YEAR	22,348	13,697
EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(47)	15
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF YEAR	$ 18,025	$ 22,348
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Non cash activity - Purchase of property and equipment in payables	$ -	$ 6
Right of use assets obtained in exchange for new operating lease liabilities	$ -	$ 240
RECONCILIATION OF CASH, CASH EQUIVALENTS, AND RESTRICTED CASH REPORTED IN THE STATEMENT OF FINANCIAL POSITION		
Cash and cash equivalents	$ 17,665	$ 21,986
Restricted cash included in current assets	360	-
Restricted bank deposits included in non-current assets	-	362
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 18,025	$ 22,348
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest received	$ 225	$ 141
Interest paid	$ -	$ (2)

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

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES:

a. General

Vascular Biogenics Ltd. ("VBL" or the "Company") is a biotechnology company developing targeted medicines for immune-inflammatory diseases. VBL's lead immunology product candidate, VB-601, is a clinic ready targeted antibody for immune-inflammatory applications expected to enter a Phase 1 first-in-human trial, subject to the Company's ongoing strategic process.

On July 19, 2022, VBL announced top-line results from its Phase 3 OVAL clinical trial. The trial did not meet the primary endpoints of achieving a statistically significant improvement in progression-free survival ("PFS") or overall survival ("OS") and VBL discontinued the trial. VBL has conducted a strategic review of the ofra-vec program and ceased further development of ofra-vec in all indications. As these results are considered a triggering event, VBL performed an impairment test on all of its assets in the third quarter of 2022. The Company concluded that the value of its manufacturing facility is in excess of its carrying value and therefore is not subject to impairment. Upon evaluation of the remaining assets and liabilities, (i) VBL wrote off all long term prepaids assets, (ii) recorded severance provisions (including additional termination benefits) for the remaining full time employees, (iii) modified the term of the lease right-of- use assets and liabilities due to reassessment of exercise of the renewal option and reduced the remaining period from 4.5 years to 18 months, and (iv) recognized the remaining deferred revenue from the exclusive license agreement with Nanocarrier for the development, commercialization, and supply of ofra-vec in Japan for all indications (the "NanoCarrier License"), which has since been terminated.

In August 2022, VBL announced an organizational streamlining designed to reduce operating expenses and preserve capital. As a result, to date, the Company reduced its workforce by approximately 84% of its full-time employees, and its board of directors was also reduced from nine to six members. In August 2022, VBL also announced that it was exploring strategic alternatives to enhance shareholder value and engaged Chardan Capital Markets, LLC ("Chardan") as its exclusive financial advisor to assist in this process. Potential strategic options explored or evaluated as part of the process included, but were not limited to merger, reverse merger, other business combination, sale of assets, licensing, or other strategic transactions. As a result of this process, on February 15, 2023, VBL entered into an Asset Purchase Agreement (the "Purchase Agreement") providing for the sale of its rights to lease the Modi'in facility along with certain tangible assets and equipment located therein for $7.1 million in cash, which sale closed on March 9, 2023. In addition, and on February 22, 2023, VBL entered into an Agreement and Plan of Merger with Notable Labs, Inc. ("Notable") and a wholly-owned merger subsidiary (the "Merger Agreement"), see more fully described below.

On February 22, 2023, VBL entered into Merger Agreement with Notable and Vibrant Merger Sub, Inc., a Delaware corporation and VBL's direct, wholly-owned subsidiary ("Merger Sub"), pursuant to which, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Notable will be merged with and into Merger Sub (such transaction, the "Merger") at the effective time of the Merger (the "Effective Time"), with Notable continuing after the Merger as the surviving corporation and a wholly-owned subsidiary of VBL. The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

At the Effective Time, each outstanding share of Notable capital stock will be converted into the right to receive VBL ordinary shares, as set forth in the Merger Agreement. Under the exchange ratio formula in the Merger Agreement, immediately following the Effective Time, the former Notable securityholders are expected to own approximately 76% of the VBL ordinary shares on a fully diluted basis and subject to adjustment and securityholders of VBL as of immediately prior to the Effective Time are expected to own approximately 24% of the VBL ordinary shares on a fully diluted basis and subject to adjustment. Under certain circumstances further described in the Merger Agreement, the ownership percentages may be adjusted upward or downward based on the level of VBL's net cash at the closing of the Merger, and the terms and net proceeds of Notable's pre-merger financing. There can be no assurances as to VBL's level of net cash between the signing of the Merger Agreement and the closing of the Merger.

The Merger Agreement contains a customary "no-shop" provision under which neither VBL nor Notable is permitted to (i) solicit any alternative acquisition proposals, (ii) furnish any non-public information to any person in connection with or in response to any alternative acquisition proposal, (iii) engage in any negotiations or discussions with any person with respect to any alternative acquisition proposal, (iv) approve, endorse or recommend any alternative acquisition proposal, or (v) execute or enter into any agreement relating to any alternative acquisition proposal. The "no-shop" provision is subject to certain exceptions that permit the board of directors of either party to comply with its fiduciary duties, which, under certain circumstances, would enable VBL or Notable to provide information to, and enter into discussions or negotiations with, third parties in response to any alternative acquisition proposals.

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

The Merger Agreement contains customary representations, warranties and covenants made by Notable and VBL, including representations relating to obtaining the requisite approvals of the securityholders of Notable and VBL, agreements relating to indemnification of directors and officers, and covenants relating to Notable's and VBL's conducting of their respective businesses between the date of signing the Merger Agreement and the Effective Time.

The Merger Agreement provides each of VBL and Notable with specified termination rights, and further provides that, upon termination of the Merger Agreement under specified circumstances, the terminating party may be required to pay the other party a termination fee of $2,500,000. In addition, in connection with certain terminations of the Merger Agreement, VBL may be required to pay Notable's out-of-pocket fees and expenses up to $500,000, or Notable may be required to pay VBL's out-of-pocket fees and expenses up to $500,000.

The Merger Agreement provides that, immediately following the Effective Time, the board of directors of the combined company will consist of up to seven directors, with one director designated by us. Upon the closing of the transaction, the combined company will be led by Notable's chief executive officer and executive management team. In connection with the Merger, VBL will seek to amend its articles of incorporation to: (i) effect an increase of its registered share capital and/or effect a reverse split of its ordinary shares at a ratio to be determined; (ii) change its name to "Notable Labs, Ltd."; and (iii) make other such changes as mutually agreeable to VBL and Notable.

VBL and Notable's obligations to consummate the Merger are subject to the satisfaction or waiver of customary closing conditions, including, among others, obtaining the requisite approval of VBL's shareholders, obtaining the requisite approval of Notable's stockholders, proceeds of Notable's pre-closing financing, net of certain specified expenses, not being less than $5,000,000 and VBL's net cash not being less than $15,000,000.

In connection with the execution of the Merger Agreement, VBL and Notable entered into shareholder support agreements with their current directors and executive officers who collectively beneficially own or control an aggregate of approximately 2% of VBL's outstanding ordinary shares. These shareholder support agreements provide that, among other things, each of the shareholders has agreed to vote or cause to be voted all of its ordinary shares beneficially owned by such shareholder in favor of the issuance of VBL's ordinary shares in the Merger at the VBL shareholder meeting to be held in connection with the Merger.

In August 2022, VBL also received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market LLC, or Nasdaq, notifying that the Company's listed securities did not maintain the minimum bid price requirement of $1.00 per ordinary share for continued listing on the Nasdaq Global Market for a period of 30 consecutive business days as required under Nasdaq Listing Rule 5450(a)(1). The Nasdaq deficiency letter does not result in the immediate delisting of VBL's ordinary shares, and the Company's ordinary shares will continue to trade uninterrupted under the symbol "VBLT." Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), VBL had a compliance period of 180 calendar days, or until February 27, 2023, to regain compliance with Nasdaq's minimum bid price requirement. If at any time during the compliance period, the Company's ordinary shares had a closing bid price of at least $1.00 for 10 consecutive business days, Nasdaq would have provided the Company with a written confirmation of compliance and the matter would have closed. The Company did not regain compliance by February 27, 2023, requested the transfer of its listing to Nasdaq's Capital Market and received an additional 180 day period to regain compliance. Further, under Nasdaq Listing Rules 5810(c)(1) and 5810(c)(3)(A)(iii), if VBL's trading price falls below $0.10 for ten consecutive trading days, the Company will receive a Staff Delisting Determination providing for automatic suspension and delisting. VBL can appeal in writing to be granted an exception to remain listed for up to an additional 180 day period to regain compliance if the Hearings Panel believes the Company will be able to regain compliance with the $1.00 minimum bid price requirement within that timeframe. VBL intends to monitor the closing bid price of its ordinary shares and may, if appropriate, consider available options to regain compliance with the minimum bid price requirement. If the Company does not regain compliance with the bid price requirement by the end of the second compliance period, or if its trading price falls below $0.10 for ten consecutive trading days, VBL's stock will be subject to delisting.

The Merger with Notable (discussed below) is considered a "change in control" under Nasdaq's rules, and the combined company will need to satisfy all of Nasdaq's initial listing criteria. If the merger is consummated and the combined entity fails to either qualify for listing or timely complete Nasdaq's initial listing process prior to consummation, this could also result in a suspension of trading and possible delisting.

In August 2022, VBL received $1.1 million as part of the grant from the European Innovation Council ("EIC") for development of ofra-vec.

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

Since inception, VBL has incurred significant losses, and it expects to continue to incur significant expenses and losses for at least the next several years. As of December 31, 2022, VBL had an accumulated deficit of $294.4 million and cash, cash equivalents, short-term bank deposits and restricted bank deposits of $21.1 million. Based on its current cash resources, and successful implementation of its reduction in workforce, VBL believes its current cash will be sufficient to fund estimated operating expenses and capital expenditure requirements for at least 12 months from the date of the filing of these financial statements. VBL is undertaking a review of its strategic options and any transaction resulting from such review may impact this projection. Further, its losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of its clinical trials, the receipt of payments under any future collaboration agreements it may enter into, its expenditures on other research and development activities, as well as any strategic options it may pursue. VBL may seek to raise more capital to pursue additional activities, including through a combination of private and public equity offerings, debt, government grants, strategic collaborations and licensing arrangements. Additional financing may not be available when VBL needs it or may not be available on terms that are favorable to VBL.

If VBL is unable to raise additional funds through equity or debt financings or through strategic alliances when needed, or conclude any strategic transaction for its assets to maximize shareholder value, it may be required to delay, limit, reduce or terminate its product development efforts or cease operations altogether. Failure to obtain additional financing will have a material, adverse impact on the Company's business operations and there can be no assurance that VBL will be able to obtain the needed financing to achieve its goals on acceptable terms or at all.

b. Basis of preparation of the financial statements

The Company's financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

c. Use of estimates in the preparation of financial statements

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results may differ from those estimates.

d. Functional and presentation currency:

1) Functional and presentation currency

The U.S. dollar ("dollar") is the currency of the primary economic environment in which the operations of the Company are conducted. Accordingly, the functional and presentation currency of the Company and its U.S. subsidiary is the dollar.

2) Transactions and balances

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in non-dollar currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-dollar transactions and other items in the statements of operations (indicated below), the following exchange rates are used: (i) for transactions - exchange rates at transaction dates or average rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation and amortization, etc.) - historical exchange rates.

All foreign exchange gains and losses are presented in the statements of operations within financial income or expenses.

e. Cash, cash equivalents and restricted cash deposits

The Company considers all short-term, highly liquid investments, to be a cash or cash equivalents, which includes short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash, in addition to restricted cash required to be set aside for operating lease contractual agreements and recorded in current assets on the balance sheet.

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

f. Property, plant and equipment:

1) All property and equipment (including leasehold improvements) are stated at cost less accumulated depreciation and impairment. Cost includes expenditures that are directly attributable to the acquisition of the items.

Repairs and maintenance are recorded in the statement of comprehensive loss during the period in which they are incurred.

2) The assets are depreciated using the straight-line method to allocate their cost over their estimated useful lives. Annual rates of depreciation are as follows:

	Years
Laboratory equipment	7-15
Computers	3-4
Office furniture and equipment	15

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

3) Gains and losses on disposals are determined by comparing proceeds with the associated carrying amount. These are included in the statements of operations.

g. Held-for-sale

A long-lived asset (disposal group) to be sold shall be classified as held for sale in the period in which all of the following criteria are met:

A. Management, having the authority to approve the action, commits to a plan to sell the asset (disposal group).
B. The asset (disposal group) is available for immediate sale in its present condition subject only to terms that are usual and customary for sales of such assets (disposal groups).
C. An active program to locate a buyer and other actions required to complete the plan to sell the asset (disposal group) have been initiated.
D. The sale of the asset (disposal group) is probable, and transfer of the asset (disposal group) is expected to qualify for recognition as a completed sale, within one year. The term probable refers to a future sale that is likely to occur.
E. The asset (disposal group) is being actively marketed for sale at a price that is reasonable in relation to its current fair value.
F. Actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn.

In October 2022, VBL decided to sell the Company's long-lived assets related to the GMP manufacturing facility in Israel. Per ASC 360-10, from that date forward these assets are measured at the lower of their carrying amount or fair value less cost to sell.

h. Impairment of long-lived assets

Assets that are subject to depreciation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the sum of expected future cash flows (undiscounted and without interest charges) of the assets is less than the carrying amount of such assets, an impairment loss would be recognized. The assets would be written down to their estimated fair values, calculated based on the present value of expected future cash flows (discounted cash flows), or some other fair value measure.

Through December 31, 2022, no impairment has been recognized (see also note 1).

i. Deferred income tax

Deferred taxes are recognized using the asset and liability method on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements.

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future. Given the Company's losses, the Company has provided a full valuation allowance with respect to its deferred tax assets.

j. Uncertainty in income tax

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained based on technical merits. If this threshold is met, the second step is to measure the tax position as the largest amount that has more than a 50% likelihood of being realized upon ultimate settlement.

k. Employee benefits:

a. Post-employment benefit obligation

Israeli labor laws and the Company's agreements require the Company to pay retirement benefits to employees terminated or leaving their employment in certain other circumstances. Most of the Company's employees are covered by a defined contribution plan under Section 14 of the Israel Severance Pay Law from the beginning of their employment with the Company.

With respect to the remaining employees, which are not covered by a defined contribution plan under Section 14 of the Israel Severance Pay Law only from January 1, 2010, the Company records an asset and liability in its balance sheet.

b. Vacation and recreation pay

Under Israeli law, each employee is entitled to vacation days and recreation pay, both computed on an annual basis. The entitlement is based on the length of the employment period. US employees are offered a similar benefit. The Company recognizes a liability and expense for vacation and recreation pay based on the entitlement of each employee.

k. Share-based compensation

The Company accounts for employees' and directors' share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period.

The Company elected to recognize compensation costs for awards conditioned only on continued service that have a graded vesting schedule using the accelerated method over the related service period.

Share based payments to employees and directors were measured by reference to the fair value of the options and restricted share (hereinafter "RSUs") granted at date of grant.

The Company calculates the fair value of stock-based option awards on the date of grant using the Black-Scholes option pricing model. This option pricing model requires estimates as to the option's expected term and the price volatility of the underlying stock.

The Company measures compensation expense for the restricted stock units based on the market value of the underlying stock at the date of grant. Performance vesting conditions are included in assumptions about the number of options and RSU's that are expected to vest.

The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied.

When options are exercised, the Company issues new shares, with proceeds less directly attributable transaction costs recognized as share capital (par value) and additional paid in capital.

The Company has elected to recognize forfeitures as they occur.

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

l. Contingencies:

Certain conditions may exist as of the date of the financial statements, which may result in a loss to the Company, but which will only be resolved when one or more future events occur or fail to occur. If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability is recorded as accrued expenses in the Company's financial statements. If the assessment indicates that a potential material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, together with an estimate of the range of possible loss if determinable and material are disclosed.

As of December 31, 2022, no contingent liabilities have been recognized.

m. Revenue from contracts with customers: ***General***

The Company recognizes revenues from the NanoCarrier License Agreement ("License Agreement") according to ASC 606, "Revenues from Contracts with Customers".

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company performs the following steps:

1. identify the contract with a customer;

2. identify the performance obligations in the contract;

3. determine the transaction price;

4. allocate the transaction price to the performance obligations in the contract;

5. recognize revenue when (or as) the entity satisfies a performance obligation.

Revenues from licensing agreement

According to ASC 606, a performance obligation is a promise to provide a distinct good or service or a series of distinct goods or services. A good or service promised to a customer is distinct if the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

The Company has identified two performance obligations in The License Agreement: (1) Grant of the license and use of its IP; and (2) Company's participation and consulting assistance services. In addition, there is a potential performance obligation regarding future manufacturing.

ASC 606 defines the 'Transaction Price' as the amount of consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services to a customer. The Company estimates the standalone selling prices of the services to be provided based on expected cost-plus margin approach and uses the residual approach to estimate the selling price of the license.

The Grant of the license and use of its IP performance obligation considered to be a right to use IP in accordance with ASC 606. Therefore, revenue is recognized at a point in time, upon transfer of control over the license to the licensee.

The Company's participation and consulting assistance services performance obligation is recognized as revenue over the service period, based on input method, which is costs incurred and labor hours expended.

The transaction price contains variable consideration contingent upon the licensee achieving certain milestones, as well as sales-based royalties, in accordance with the relevant agreement. Variable payments, contingent on achieving additional milestones, are included in the transaction price based on most likely amount method. Amounts included in the transaction price are recognized only when it is probable that a significant reversal of cumulative revenues will not occur, usually upon achievement of the specific milestone, in accordance with the relevant agreement. Sales-based royalties are not included in the transaction price. Rather, they are recognized as the related sale occurs, due to the specific exception of ASC 606 for sales-based royalties in licensing of intellectual properties.

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

In September 2022, the License Agreement was terminated. As VBL does not expect to generate additional revenues from the achievement of new milestones or royalties under the License Agreement, VBL recognized the remaining deferred revenue. Accordingly, during the twelve months ended December 31, 2022, VBL recognized revenue of $0.7 million.

n. Research and development expenses:

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of clinical trials, clinical trial supplies, salaries, share-based compensation expenses, payroll taxes and other employee benefits, lab expenses, consumable equipment and consulting fees. All costs associated with research and developments are expensed as incurred.

Clinical trial expenses are charged to research and development expense as incurred. The Company accrues for expenses resulting from obligations under contracts with clinical research organizations (CROs). The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. The Company's objective is to reflect the appropriate trial expense in the financial statements by matching the appropriate expenses with the period in which services and efforts are expended.

o. Government grants

Government grants, which are received from the Israeli Innovation Authority or IIA (formerly known as the Israeli Office of Chief Scientist, or the "OCS") by way of participation in research and development that is conducted by the Company, are received in installments as the program progresses based on qualified research spending. Grants received 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 is reasonable assurance the grant will be received.

In August 2022, the Company received $1.1 million as part of the €2.5 million grant from the European Innovation Council, or EIC, for development of ofra-vec. VBL may be entitled to an additional $1.4 million in grant funds for project activities conducted prior to the termination of the ofra-vec project; however, there can be no assurance that the Company will receive these funds.

The grants are deducted from the research and development expenses as the applicable costs are incurred. Research and development expenses, net, for the years ended December 31, 2022 and 2021, include participation in research and development expenses in the amount of approximately $1.2 million and $0.5 million, respectively.

p. Leases

The Company determines if an arrangement is a lease at inception. Balances related to operating leases are included in operating lease right-of-use ("ROU") assets, other current liabilities, and operating lease liabilities in the consolidated balance sheets.

The Company also elected to combine lease and non-lease components and to keep leases with an initial term of 12 months or less off the balance sheet and recognize the associated lease payments in the consolidated statements of income on a straight-line basis over the lease term.

ROU assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized as of the commencement date based on the present value of lease payments over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The discount rate for the lease is the rate implicit in the lease unless that rate cannot be readily determined. As the Company's leases do not provide an implicit rate, the Company's uses its estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term (see also note 5).

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

The Company shall reassess the lease term only if and at the point in time that any of the following occurs:

1. There is a significant event or a significant change in circumstances that is within the control of the Company that directly affects whether the Company is reasonably certain to exercise or not to exercise an option to extend or terminate the lease.
2. There is an event that is written into the contract that obliges the Company to exercise (or not to exercise) an option to extend or terminate the lease.
3. The Company elects to exercise an option even though the Company had previously determined that the Company was not reasonably certain to do so.
4. The Company elects not to exercise an option even though the Company had previously determined that the Company was reasonably certain to do so.

In September 2022, the company re-evaluated the manufacturing's lease agreement and reduced the lease period to 7 years (see also note 1) as the lease extension was no longer reasonably certain to be exercised.

q. Segment reporting

An operating segment is defined as a component that engages in business activities whose operating results are reviewed by the chief operating decision maker for the purpose of assessing performance and allocating resources and for which discrete financial information is available. The Company has one operating segment.

r. Loss per Ordinary Share

VBL complies with accounting and disclosure requirements of FASB ASC Topic 260, Earnings Per Share. Basic loss per share of common stock is computed by dividing the net loss by the weighted average number of ordinary shares (including fully vested RSUs and PSUs) outstanding during the period. Due to the existence of Ordinary shares subject to possible redemption, the Company follows the two-class method in calculating loss per share. In computing diluted earnings per share, basic earnings per share are adjusted to take into account the potential dilution that could occur upon the exercise of options and non-vested RSUs and PSUs, using the treasury stock method.

Accretion associated with the ordinary shares subject to possible redemption is excluded from loss per ordinary share.

Potentially dilutive securities have been excluded from VBL's computation of dilutive loss per share as such securities would have been anti-dilutive. There were 8,518,616 and 12,191,029 ordinary shares underlying outstanding options and warrants on December 31, 2022 and 2021, respectively.

s. Concentration of credit risks

Credit and interest risk arise from cash and cash equivalents and deposits with banks. A substantial portion of the liquid instruments of the Company are invested in short-term deposits in a leading Israeli bank. The Company estimates that since the liquid instruments are mainly invested for short-term and with a highly rated institution, the credit and interest risk associated with these balances is immaterial.

t. Recently adopted accounting pronouncements

In November 2021, the FASB issued ASU 2021-10, "Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance." ASU 2021-10 requires disclosures about transactions with a government that have been accounted for by a grant or contribution accounting model to increase transparency about the types of transactions, the accounting for the transactions, and the effect on the financial statements. The ASU is an annual disclosure effective for fiscal years beginning after December 15, 2021 and will be applied on a prospective basis. The Company evaluated the impact this new standard has on the consolidated financial statements and related disclosures and concluded there is a material impact.

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

In March 2020, the FASB issued ASU 2020-04 "Reference Rate Reform (Topic 848)—Facilitation of the Effects of Reference Rate Reform on Financial Reporting." This guidance provides optional expedients and exceptions for applying generally accepted accounting principles to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The guidance applies only to contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. This guidance is effective for all entities as of March 12, 2020 through December 31, 2024. The Company adopted the new standard effective January 2022. The Company has completed negotiations to transform the facility base rate of its EU securitization program and evaluated the potential impact of the replacement of the LIBOR benchmark on its interest rate risk management activities. The adoption of this guidance did not have a material impact on the Company's consolidated financial results of operations, financial position or cash flows.

NOTE 2 – FAIR VALUE MEASUREMENTS

The different levels of valuation of financial instruments are defined as follows:

Level 1 Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2 Observable prices that are based on inputs not quoted on active markets, but corroborated by market data or active market data of similar or identical assets or liabilities.

Level 3 Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

As of December 31, 2022 and 2021, the fair value of financial instruments (cash and cash equivalents, short term bank deposits, restricted bank deposits, other current assets and accounts payable) approximate their carrying amounts.

NOTE 3 – SHORT-TERM BANK DEPOSITS

The bank deposit as of December 31, 2022 for $3.1 million was for a term of nine months and carried interest at annual rate of 3.15%. The bank deposits as of December 31, 2021 of $31.2 million were for terms of three months to one year and carried interest at annual rates of 0.65%-0.85%.

NOTE 4 – PROPERTY AND EQUIPMENT

	December 31	
	2022	**2021**
	(in thousands)	
Cost:		
Laboratory equipment*	$ 6,778	$ 6,005
Computers	352	328
Office furniture and equipment	200	200
Leasehold improvements	$ 6,722	6,707
	$ 14,052	$ 13,240
Less:		
Accumulated depreciation*	$ 7,451	$ 6,393
Property and Equipment, net	$ 6,601	$ 6,847

*Laboratory equipment includes the finance lease (see Note 5) with a cost of $1.1 million as of December 31, 2022 and 2021. The related accumulated depreciation for the finance lease as of December 31, 2022 and 2021 was $0.8 million and $0.6 million, respectively.

Depreciation expense totaled $1.1 million and $1.3 million for the years ended December 31, 2022 and December 31, 2021, respectively.

During the year ended December 31, 2022, the Company did not dispose of any fixed assets. During the year ended December 31, 2021, the Company disposed of $0.1 million of fixed assets.

NOTE 5 – LEASES

Operating leases

1) In October 2016, the Company entered into a long-term lease contract for approximately $2.2 million over 7 years commencing May 2017 for a new facility in Modi'in, Israel with the option to extend for an additional two periods of three years each. As of 2022, due to VBL's strategic process and monetization of the facility, the Company will not utilize the extension options, reducing its right of use assets and right of use liabilities by approximately $3.5 million each. The facility houses the Company's local manufacturing facility, headquarters, discovery research and clinical development. The lease requires a restricted bank deposit of $0.4 million which is included in current assets on the balance sheet.

2) The Company maintains operating lease agreements for vehicles it uses. The lease periods are generally for three years. As a result of the 2022 organizational streamlining and accordingly the workforce reduction, the Company terminated the majority of its employee vehicle leases, reducing its operating lease assets and liabilities by approximately $0.07 million each.

Finance Lease

In July 2017, the Company entered into a long-term lease contract for approximately $1.1 million over 3 years commencing April 2018 for a laboratory water purification system used in our manufacturing process. As of 2021, the finance lease was fully amortized.

The following table sets forth data regarding the Company's leases:

	Year ended December 31,	
	2022	2021
	(in thousands)	
Lease cost		
Finance lease cost:		
Amortization of right-of-use assets	$ -	$ 168
Interest on lease liabilities	-	1
Operating lease cost	560	595
Other information		
Cash paid for amounts included in the measurement of lease liabilities:		
Financing cash flows from finance leases	$ -	$ 104
Operating cash flows from operating leases	$ 575	$ 586
Financing cash flows from finance leases	$ -	$ 1
Right-of-use assets obtained in exchange for new operating lease liabilities	$ -	$ 368

	December 31,	
	2022	2021
Weighted-average discount rate - finance leases	-	3.0%
Weighted-average discount rate - operating leases	5.7%	4.0%
Weighted-average remaining lease term – finance lease	-	-
Weighted-average remaining lease term - operating leases	1.25	4.80

NOTE 5 – LEASES (continued)

Future minimum lease payments under non-cancellable leases as of December 31, 2022 were as follows:

	Operating Leases (Dollars in thousands)
Year ending December 31,	
2023	456
2024	131
2025 and thereafter	-
Total future minimum lease payments	587
Less imputed interest	(23)
Total	$ 564

NOTE 6 – SEVERANCE PAY OBLIGATIONS

Israeli law generally requires payment of severance pay upon dismissal of an employee or upon termination of employment in certain other circumstances. The Israel pension and severance pay liability to employees are covered mainly by regular deposits with recognized pension and severance pay funds under the employees' names and through the purchase of insurance policies.

Most of the Company's employees are covered by a defined contribution plan under Section 14 of the Israel Severance Pay Law. According to the plan, the Company regularly makes payments to severance pay or pension funds without having a legal or constructive obligation to pay further contributions if the funds do not hold sufficient assets to pay all employees in the plan the benefits relating to employee service in the current and prior periods. Neither severance pay liability nor severance pay funds under Section 14 for such employees is recorded on the Company's balance sheet as the Company is relieved of its obligation upon contribution.

For certain Israeli employees, the Company accrues severance pay liability, calculated pursuant to Israeli Severance Pay Law based on the most recent salary of the employees multiplied by the number of years of employment as of the balance sheet date (the "Shut-Down method"). The liability is recorded as if it was payable at each balance sheet date on an undiscounted basis.

The Company's liability with respect to Israeli employees' is covered by monthly deposits with severance pay funds. The value of the deposited funds is based on the cash surrender value of these policies and includes profits (or loss) accumulated through the balance sheet date. The deposited funds may be withdrawn only upon the fulfillment of the obligations pursuant to Israeli Severance Pay Law or labor agreements. The amounts funded are presented separately in the balance sheet as funds in respect to employees' rights upon retirement.

The amounts of severance pay expenses were approximately $0.1 million and $0.3 million for each of the years ended December 31, 2022, and 2021, respectively, which were substantially made up of company payments to the Contribution Plans. Gains on amounts funded in respect of employee rights upon retirement for the years ended December 31, 2022 and 2021 were immaterial.

The Company expects to contribute approximately $0.1 million in the year ending December 31, 2022 to insurance companies in connection with its severance liabilities for its operations for that year, approximately all of which will be contributed to one or more Contribution Plans.

The above amounts were determined based on the employees' current salary rates and the number of years' service that will have been accumulated at their retirement date. These amounts do not include amounts that might be paid to employees that will cease working with the Company before reaching their normal retirement age.

NOTE 7 – LICENSE AND SUPPLY AGREEMENTS

In November 2017, the Company signed an exclusive license agreement with NanoCarrier Co., Ltd. for the development, commercialization, and supply of ofra-vec in Japan. VBL retains rights to ofra-vec globally except for Japan ("The License Agreement"). Under the terms of the agreement, VBL has granted NanoCarrier an exclusive license to develop and commercialize ofra-vec in Japan for all indications. VBL will supply NanoCarrier with ofra-vec, and NanoCarrier will be responsible for all regulatory and other clinical activities necessary for commercialization in Japan. In exchange, the Company received an up-front nonrefundable payment of $15.0 million, and is entitled to receive greater than $100.0 million in additional payments if certain development and commercial milestones are achieved. VBL will also receive tiered royalties on net sales. In addition, if NanoCarrier enters into a sublicense agreement, the Company would be entitled to receive royalties from the sublicense income received by NanoCarrier.

The performance obligation relating to the Company's participation and consulting assistance services during the development period is recognized over the service period. During 2022 and 2021, the Company recognized revenue in an amount of $0.7 million and $0.8 million, respectively related to the Company's participation and consulting assistance services of ofra-vec in Japan for all indications. In September 2022, the License Agreement was terminated. As VBL does not expect to generate additional revenues from the achievement of new milestones or royalties under the License Agreement, VBL expensed the remaining deferred revenue.

Revenues recognized in 2022 and 2021 were related to the Company's participation and consulting assistance services from the License Agreement. All of the revenues recognized in 2022 were included in the opening balance of the deferred revenue in the balance sheets.

NOTE 8 – COMMITMENTS:

a. In April 2011, the Company executed a Commercial License Agreement with Janssen Vaccines & Prevention B.V. ("Janssen"), for incorporating the adenovirus 5 in ofra-vec and other historical drug candidates for cancer for consideration including the following potential future payments:

- an annual license fee of €0.1 million ($0.1 million) that is linked to Consumer Price Index (in each of 2022 and 2021, the Company paid $0.1 million) continuing until the termination of the agreement, which will occur upon (i) the later of the expiration date of the last related patent or 10 years from the first commercial sale of ofra-vec or (ii) the termination of the agreement by the Company, which is permitted, upon three months' written advance notice to Janssen;

- a milestone payment of €0.4 million ($0.4 million) upon receipt of the first regulatory approval for the marketing of the first indication for each product covered under the agreement; and

- royalties of 0.5% to 2.0% on net sales.

There are no limits or caps on the amount of potential royalties. In August 2022, the Company terminated the agreement with Janssen and has no further obligations.

b. In February 2013, the Company entered into an agreement with Tel Hashomer-Medical Research, Infrastructure and Services Ltd. ("Tel Hashomer"). The agreement with Tel Hashomer provides that the Company will pay 1% of any net sales of any product covered by the intellectual property covered under the agreement and 2% of any consideration received by the Company for granting a license or similar rights to such intellectual property. Such amounts will be recorded as part of the Company's cost of revenues. In addition, upon the occurrence of an exit event such as a merger, sale of all shares or assets or the closing of an initial public offering such as the IPO, the Company is required to pay to Tel Hashomer 1% of the proceeds received by the Company or its shareholders as the case may be. Royalty and all other payment obligations under this agreement will expire once the Company has paid an aggregate sum of NIS 100 million (approximately $29 million) to Tel Hashomer by way of pay out, exit proceeds and licensing consideration. Amounts previously paid as royalties on any net sales will not be taken into account when calculating this aggregate sum. Amounts payable upon occurrence of an exit event are not considered to be probable until actual occurrence. Upon occurrence of such event, as such event does not represent a substantive milestone with regard to the Company's intellectual property, the amount to be paid is recorded in the Statement of comprehensive loss under research and development costs.

Through December 31, 2022, the Company paid Tel Hashomer a total amount of $0.7 million in consideration for the payments received for granting the licenses or similar rights to this intellectual property. As of December 31, 2022, the Tel Hashomer agreement was terminated, and the Company has no further commitments.

NOTE 8 – COMMITMENTS (continued):

c. The Company is committed to pay royalties to the Government of Israel on proceeds from sales of products in the research and development of which the Government participates by way of grants. At time the grants were received, successful development of the related project was not assumed. In the case of failure of the project that was partly financed by the Government of Israel, the Company is not obligated to pay any such royalties. As the Company did not meet the trial's primary endpoints and accordingly discontinued the trial in 2022, VBL is not pursuing further development with an IIA funded project; and therefore, the Company is no longer obligated to pay additional royalties. Under the terms of the Company's funding from the Israeli Government, royalties of 3%-3.5% are payable on sales of products developed from projects funded up to 100% of the amount of the grant received by the Company (dollar linked) with the addition of an annual interest. As of December 31, 2022, the total additional royalty amount that may be payable by the Company, before the additional interest, is approximately $29.4 million ($38.4 million including interest). To date, the Company has paid the IIA approximately $0.6 million in royalties.

In addition, under the Research Law, the Company is prohibited from transferring, including by way of license, the IIA-financed technologies and related intellectual property rights and know-how outside of the State of Israel, except under limited circumstances and only with the approval of the IIA Research Committee. The Company may not receive the required approvals for any proposed transfer and, even if received, may be required to pay the IIA a portion of the consideration that it receives upon any sale of such technology to a non-Israeli entity up to 600% of the grant amounts plus interest.

NOTE 9 – SHARE CAPITAL:

a. Common Stock

The Company has authorized 200 million shares of common stock, NIS 0.01 par value per share as of December 31, 2022 and 150 million shares of common stock, NIS 0.01 par value per share as of December 31, 2021. Each share of common stock is entitled to one voting right. Common stock owners are entitled to dividends when funds are legally available and declared by the Company's board of directors.

b. Common Stock Offerings

On January 14, 2021, the Company entered into an ordinary share purchase agreement of up to $20 million of VBL's ordinary shares, par value NIS 0.01 per share, with an institutional investor. The ordinary shares may be sold from time to time based on our notice to the investor over the 30-month term of the purchase Agreement. On December 6, 2022, the ordinary share purchase agreement terminated. During the term of the ordinary share purchase agreement, the Company issued an aggregate of 1,400,000 shares for gross proceeds of approximately $3.0 million.

On April 9, 2021, VBL entered into an underwriting agreement pursuant to which the Company issued (a) 5,150,265 of its ordinary shares to certain investors at a price of $1.90 per ordinary share and (b) pre-funded warrants to purchase 8,050,000 ordinary shares at price of $1.89 per pre-funded warrant with an exercise price of each pre-funded warrant equal to $0.01 per share. In addition, the underwriters exercised an option to purchase additional shares and purchased 1,751,525 additional ordinary shares. Net proceeds from the issuance and sale of the 6,901,790 ordinary shares and 8,050,000 pre-funded warrants was approximately $26.4 million, after deducting the underwriting discounts and commissions and the estimated offering expenses.

On February 11, 2022, the Company entered into an Open Market Sale Agreement℠ with Jefferies LLC ("Jefferies"), to offer and sell from time to time its ordinary shares, NIS 0.01 par value, having an aggregate offering price of up to $50.0 million (the "ATM Facility"). From February 11, 2022 through March 10, 2023, no shares were sold under the ATM Facility.

In February 2022, the 615,366 shares that were classified as redeemable shares in 2021 were no longer subject to redemption and were classified as shareholders' equity.

NOTE 9 – SHARE CAPITAL: (continued):

c. Warrants

There were no outstanding warrants as of December 31, 2022:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2020.....	15,726,378	$ 2.38	
Exercised	(11,523,997)	1.57	
Expired.....	(1,250,000)	7.50	
Outstanding as of December 31, 2021.....	2,952,381	3.00	
Expired.....	(2,952,381)	3.00	
Outstanding as of December 31, 2022.....	-	-	-
Exercisable as of December 31, 2022.....	-	-	-

During the years ended December 31, 2022 and 2021, no additional warrants were issued.

d. Pre-funded Warrants

In April 2021, the Company issued 8,050,000 pre-funded warrants in lieu of ordinary shares in an underwritten public offering at a price per share of $1.89. The pre-funded warrants are exercisable for $0.01 per share and have no expiration date. As of December 31, 2022, none of the pre-funded warrants have been exercised.

e. Stock-Based Compensation

In February 2000, the Company's Board of Directors approved an option plan (the "Plan") as amended through 2008. Under the Plan, the Company reserved up to 1,423,606 Ordinary Shares of NIS 0.01 par value of the Company for allocation to employees and non-employees. Each option provides the holder the right to exercise such option and acquire one Ordinary Share per option. Any option granted under the Plan that is not exercised within ten years from the date upon which it becomes exercisable, will expire.

In April 2011, the Company's board of directors approved a new option plan (the "New Plan"). Under the New Plan, the Company reserved up to 766,958 Ordinary Shares (of which 159,458 Ordinary Shares shall be taken from the unallocated pool reserved under the Plan) for allocation to employees and non-employees. Any option which was granted under the New Plan and was not exercised within twenty years from the date when it becomes exercisable, will expire.

In September 2014, the Company's shareholders approved the adoption of the Employee Share Ownership and Option Plan (2014) ("2014 Plan") effective as of the closing of the public offering. Under the 2014 Plan, the Company reserved up to 928,000 Ordinary Shares (of which 28,000 Ordinary Shares shall be taken from the unallocated pool reserved under the New Plan). The Ordinary Shares to be issued upon exercise of the options confer the same rights as the other Ordinary Shares of the Company, immediately upon allotment. Any option which was granted under the 2014 Plan and was not exercised within twenty years from the date when it becomes exercisable, will expire.

Effective February 13, 2022, the board of directors of VBL approved the adoption of the Inducement Plan (2022) to reserve an additional two million (2,000,000) of VBL's ordinary shares, NIS 0.01 par value per ordinary share, to be exclusively for grants of awards to individuals who were not previously employees or non-employee directors of VBL (or following a bona fide period of non-employment with VBL), as an inducement material to each such individual's entry into employment with VBL within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules (Rule 5635(c)(4)). The Inducement Plan (2022) was approved by the board of directors without shareholder approval pursuant to Nasdaq Listing Rule 5635(c)(4). The term of each option granted under this plan will be determined by the board of directors, but no option shall be exercisable more than 10 years from the date of its grant.

Option exercise prices and vesting periods are determined by the board of directors of the Company on the date of the grant.

NOTE 9 – SHARE CAPITAL: (continued):

The options are subject to the terms stipulated by section 102(b)(2) of the Ordinance. According to these provisions, the Company will not be allowed to claim as an expense for tax purposes the amounts credited to the employees as a capital gain benefit in respect of the options granted.

Options granted to related parties or non-employees of the Company are governed by Section 3(i) of the Ordinance. The Company will be allowed to claim as an expense for tax purposes the amounts equal to the expenses it recorded in the financial statements in the year in which the related parties or non-employees exercised the options into shares.

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of comprehensive loss for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
	U.S. dollars in thousands	
General and administrative	$ 2,188	$ 1,194
Research and development	367	774
Total	$ 2,555	$ 1,968

Stock Options

Below is a table summarizing the options issued and outstanding as of and for the years ended December 31, 2022 and 2021:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Aggregate Intrinsic Value
Outstanding at December 31, 2020	7,435,360	$ 2.52		
Granted	1,794,787	2.29		
Forfeited	(65,500)	3.01		
Outstanding at December 31, 2021(1)	9,164,647	2.49		
Granted	1,264,189	0.80		
Exercised	(388,909)	0.05		
Forfeited	(3,221,311)	2.34		
Outstanding at December 31, 2022 (1)	6,818,616	2.07	14.77	$ 0
Exercisable as of December 31, 2022	4,735,356	$ 2.89	14.62	$ 0

(1) Excluding RSUs of 1,700,000 and 74,001 for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, the unrecognized compensation costs of $1.5 million will be recognized over an estimated weighted-average amortization period of 1.8 years.

The intrinsic value of stock options exercised during the years ended December 31, 2022 and 2021 was $0.09 million and $0, respectively.

The weighted average grant date fair value of options granted during the year ended December 31, 2022 and 2021 was $1.49 and $1.90.

NOTE 9 – SHARE CAPITAL: (continued):

Key assumptions used to estimate the fair value of the stock options granted during the years ended December 31, 2022 and 2021 included:

	Year Ended December 31,	
	2022	**2021**
Expected term of options (years)	5.9-11	11
Expected common stock price volatility	91.22%	91%
Risk-free interest rate	1.5% - 3.3%	1.48%-1.64%
Expected dividend yield	—	—

f. Restricted Stock Units

Below is a table summarizing the restricted stock units granted and outstanding as of and for the year ended December 31, 2022 and 2021:

	Restricted Stock Units	**Weighted Average Grant Date Fair Value Price**
Unvested as of December 31, 2020	102,334	$ 5.47
Vested	(28,333)	4.20
Unvested as of December 31, 2021	74,001	6.45
Granted	1,700,000	0.24
Forfeited	(74,001)	6.45
Unvested as of December 31, 2022	1,700,000	0.24
Total unrecognized expense remaining	$ 153,287	0.24
Weighted-average years expected to be recognized over	0.25	

NOTE 10 – TAXES ON INCOME

a. Measurement of results for tax purposes

The Company as a "foreign-investment company" measures its results for tax purposes in dollar based on Income Tax Regulations (Bookkeeping Principles of Foreign Invested Companies and of Certain Partnerships and the Determination of Their Taxable Income), 1986.

b. Tax rates

The Company is taxed according to Israeli tax laws. The taxable income of the Company, other than income from Benefited Enterprises (see c below), is subject to the regular Israeli corporate tax rate, which is currently 23%.

c. Tax benefits under the Law for the Encouragement of Capital Investments, 1959 (the "Investment Law")

Under the Investment Law, including Amendment No. 60 to the Investment Law that was published in April 2005, by virtue of the Benefited Enterprise program for certain of its production facilities, the Company may be entitled to various tax benefits.

The main benefit arising from such status is the reduction in tax rates on income derived from a Benefited Enterprise. The extent of such benefits depends on the location of the enterprise. Since the Company's facilities are not located in "national development zone A," income derived from Benefited Enterprises will be tax exempt for a period of two years and then have a reduced tax rate for a period of up to an additional eight years.

The period of tax benefits, as described above, is limited to 12 years from the beginning of the Benefited Enterprise election year (2012). As of December 31, 2022, the period of benefits has not yet commenced.

NOTE 10 – TAXES ON INCOME (continued):

In the event of distribution or deemed distribution of dividends from income, which was tax exempt as above, the amount distributed will be subject to the tax rate it was exempted from.

The Company is entitled to claim accelerated depreciation in respect of equipment used by the Benefited Enterprises during five tax years.

Entitlement to the above benefits is conditioned upon the Company fulfilling the conditions stipulated by the Investment Law and regulations published thereunder.

In the event of failure to comply with these conditions, the benefits may be canceled and the Company may be required to apply the regular tax depreciation rates and pay tax on the income in question at the regular corporate tax rates with the addition of linkage differences to the Israeli consumer price index and interest.

The Investment Law was amended as part of the Economic Policy Law for the years 2011-2012 (the "Amendment"), which became effective on January 1, 2011.

The Amendment sets alternative benefit tracks to the ones currently in place under the provisions of the Investment Law, including a reduced corporate tax rate. Tax rate for "Preferred Enterprise" income of companies not located in national development zone A is 16% for fiscal year 2014 and thereafter.

The benefits are granted to companies that qualify under criteria set forth in the Investment Law; for the most part, those criteria are similar to the criteria that have existed in the Investment Law prior to its amendment and the benefit period is unlimited in time. However, in accordance with the Amendment, the classification of licensing income as Preferred income may be subject to the issuance of a pre-ruling by the Israel Tax Authority.

Additional amendments to the Investment Law became effective in January 2017 (the "2017 Amendment"). Under the 2017 Amendment, and provided the conditions stipulated therein are met, income derived by Preferred Companies from 'Preferred Technological Enterprises' ("PTE") (as defined in the 2017 Amendment), would be subject to reduced corporate tax rates of 7.5% in Development Zone "A" and 12% elsewhere, or 6% in case of a 'Special Preferred Technological Enterprise' ("SPTE") as defined in the 2017 Amendment) regardless of the company's geographical location within Israel. A Preferred Company distributing dividends from income derived from its PTE or SPTE, would subject the recipient to a 20% tax (or lower, if so provided under an applicable tax treaty). The 2017 Amendment further provides that, in certain circumstances, a dividend distributed to a corporate shareholder who is not an Israeli resident for tax purposes would be subject to a 4% tax (if at least 90% of the shares of the distributing company are held by one or more non-Israeli resident corporations). Such taxes would generally be withheld at source by the distributing company.

On June 14, 2017, the Encouragement of Capital Investments Regulations (Preferred Technology Income and Capital Profits for a Technological Enterprise), 2017 (the "Regulations") were published, which adopted Action 5 under the base erosion and profit shifting ("BEPS") regulations. The Regulations describe, inter alia, the mechanism used to determine the calculation of the benefits under the PTE and under the SPTE Regime and determine certain requirements relating to documentation of intellectual property for the purpose of the PTE. According to these provisions, a company that complies with the terms under the PTE regime may be entitled to certain tax benefits with respect to income generated during the company's regular course of business and derived from the preferred intangible asset (as determined in the Investments Law), excluding income derived from intangible assets used for marketing and income attributed to production activity. In the event that intangible assets used for marketing purposes generate over 10% of the PTE's income, the relevant portion, calculated using a transfer pricing study, would be subject to regular corporate income tax. If such income does not exceed 10%, the PTE will not be required to exclude the marketing income from the PTE's total income. The Regulations set a presumption of direct production expenses plus 10% with respect to income related to production, which can be countered by the results of a supporting transfer pricing study. Tax rates applicable to such production income expenses will be similar to the tax rates under the Preferred Enterprise regime, to the extent such income would be considered as eligible. In order to calculate the preferred income, the PTE is required to take into account the income and the research and development expenses that are attributed to each single preferred intangible asset. Nevertheless, it should be noted that the transitional provisions allow companies to take into account the income and research and development expenses attributed to all of the preferred intangible assets they have. Under the Regulations, the Company's corporate tax rate is expected to be between 12% to 16%.

NOTE 10 – TAXES ON INCOME (continued):

Under the transitional provisions of the Investment Law, a company is allowed to continue to enjoy the tax benefits available under the Investment Law prior to its amendment until the end of the period of benefits, as defined in the Investment Law.

In each year during the period of benefits of its Benefited Enterprise, the Company will be able to opt for application of the Amendment, thereby making available to itself the tax rate described above. The Company's election to apply the Amendment is irrevocable.

As of December 31, 2022, the Company's management decided not to adopt the application of the Amendment.

There is no assurance that future taxable income of the Company will qualify as Benefited, Preferred or Preferred Technological income or that the benefits described above will be available to the Company in the future.

d. Losses for tax purposes carried forward to future years

The balance of carry forward losses of the Company as of December 31, 2022 is $250.5 million. Under Israeli tax laws, carryforward tax losses have no expiration date.

Deferred tax assets on losses for tax purposes carried forward to subsequent years are recognized if utilization of the related tax benefit against a future taxable income is expected.

As the achievement of required future taxable income is not likely, the Company recorded a full valuation allowance.

e. Tax assessments

The Company has tax assessments that are considered to be final through tax year 2017.

f. Deferred Taxes

The following table presents summary of information concerning the Company's deferred taxes as of December 31, 2022 and December 31, 2021.

December 31

	2022	2021
	U.S. dollars in thousands	
In respect of:		
Net operating loss carry forwards	57,618	51,070
Research and development expenses	4,710	4,310
Other timing differences	586	309
Less – valuation allowance	(62,914)	(55,690)
Net deferred tax assets	-	-

Deferred taxes are computed using the tax rates expected to be in effect when those differences reverse.

The changes in valuation allowance are comprised as follows:

	Year ended December 31,	
	2022	2021
	(U.S. dollars in thousands)	
Balance at the beginning of year	$ 55,690	$ 49,172
Additions during the year	7,224	6,158
Balance at end of year	$ 62,914	$ 55,690

NOTE 10 – TAXES ON INCOME (continued):

Losses for tax purposes carried forward to future years:

The main reconciling item between the statutory tax rate of the Company and the effective rate is the provision for a full valuation allowance in respect of tax benefits from carry forward tax losses due to the uncertainty of the realization of such tax benefits and the Company's three year cumulative loss position (see above).

NOTE 11 – SUPPLEMENTARY FINANCIAL INFORMATION:

	December 31	
	2022	2021
	U.S. dollars in thousands	
a. Other current assets:		
Institutions – VAT	$ 102	$ 280
Prepaid expenses	954	1,217
Government grants receivable	-	185
Other	14	15
	$ 1,070	$ 1,697
b. Accounts payable-other:		
Accrued expenses	$ 2,925	$ 3,611
Employee-related accrued expenses(1)	2,209	489
Provision for vacation	225	308
	$ 5,359	$ 4,408

(1) Includes $1.9 million of severance provision for remaining employee terminations.

NOTE 12 – LOSS PER SHARE:

Basic and diluted loss per share:

Basic

Basic loss per share is calculated by dividing the result attributable to equity holders of the Company by the weighted average number of Ordinary Shares in issue during the year.

Diluted

All Ordinary Shares underlying outstanding options, RSU's and warrants have been excluded from the calculation of the diluted loss per share for the years ended December 31, 2022 and 2021 since their effect was anti-dilutive. The following potentially dilutive securities outstanding for the year ended December 31, 2022 and 2021 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	As of December 31,	
	2022	2021
Common stock purchase options	6,818,616	9,164,647
Restricted stock units	1,700,000	74,001
Common stock purchase warrants	-	2,952,381
	8,518,616	12,191,029

NOTE 12 – LOSS PER SHARE: (continued):

	Year ended December 31	
	2022	**2021**
Basic and diluted:		
Loss attributable to equity holders of the Company	$ 32,304	$ 29,920
Weighted average number of ordinary shares in issue	77,554,740	66,346,506
Loss per ordinary share	$ 0.42	$ 0.45

NOTE 13 – SUBSEQUENT EVENTS:

a. On February 15, 2023, VBL entered into an Asset Purchase Agreement which closed on March 9, 2023. For more details see Note 1.

b. On February 22, 2023, VBL entered into Merger Agreement with Notable and Vibrant Merger Sub, Inc., a Delaware corporation and VBL's direct, wholly-owned subsidiary ("Merger Sub"). For more details see Note 1.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

VASCULAR BIOGENICS LTD.

Date: March 14, 2023

By: */s/ Dror Harats*
Dror Harats
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dror Harats and Sam Backenroth, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Dror Harats Dror Harats	Chief Executive Officer and Director	March 14, 2023
/s/ Sam Backenroth Sam Backenroth	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 14, 2023
/s/ Marc Kozin Marc Kozin	Chairman of the Board of Directors	March 14, 2023
/s/ Ruth Alon Ruth Alon	Director	March 14, 2023
/s/ Shmuel Ben Zvi Shmuel Ben Zvi	Director	March 14, 2023
/s/ David Hastings David Hastings	Director	March 14, 2023
/s/ Michael Rice Michael Rice	Director	March 14, 2023