

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

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended December 31, 2020

OR

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

OR

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

Date of event requiring this shell company report: Not applicable

For the transition period from _____ to _____

Commission file number 001-36581

Vascular Biogenics Ltd.

(Exact name of registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

Israel

(Jurisdiction of incorporation or organization)

8 HaSatat St

Modi'in

Israel 7178106

(Address of principal executive offices)

Dror Harats, Chief Executive Officer

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Israel 7178106

Tel: +972-8-9935000

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

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 each	VBLT	The Nasdaq Stock Market LLC
Title of Each Class	Name of Each Exchange on which Registered	
Ordinary Shares, par value NIS 0.01 each	The NASDAQ Stock Market LLC	

Securities registered or to be registered pursuant to Section 12(g) of the Act. None
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None

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

As of December 31, 2020, the Registrant had 48,187,463 Ordinary Shares outstanding.

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

If this report is an annual report or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes [] No [X]

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 [X] No []

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files) Yes [X] No []

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer, or an emerging growth company.

See definition of “large accelerated filer,” “accelerated filer,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer []
Emerging Growth Company []

Accelerated filer []

Non-accelerated filer [X]

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

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

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

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

U.S. GAAP [X]

International Financing Reporting Standards as issued
by the International Accounting Standards Board []

Other []

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

Item 17 [] Item 18 []

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [] No [X]

TABLE OF CONTENTS

PART I	5
Item 1. Identity of Directors, Senior Management and Advisers	5
Item 2. Offer Statistics and Expected Timetable	5
Item 3. Key Information	5
Item 4. Information on the Company	35
Item 4A. Unresolved Staff Comments	48
Item 5. Operating and Financial Review and Prospects	48
Item 6. Directors, Senior Management and Employees	58
Item 7. Major Shareholders and Related Party Transactions	71
Item 8. Financial Information	73
Item 9. The Offer and Listing	73
Item 10. Additional Information	74
Item 11. Quantitative and Qualitative Disclosures About Market Risk	88
Item 12. Description of Securities Other Than Equity Securities	88
PART II	89
Item 13. Defaults, Dividend Arrearages and Delinquencies	89
Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds	89
Item 15. Controls and Procedures	89
Item 16. [Reserved]	90
Item 16A. Audit committee financial expert	90
Item 16B. Code of Ethics	90
Item 16C. Principal Accountant Fees and Services	90
Item 16D. Exemptions from the Listing Standards for Audit Committees	90
Item 16E. Purchase of Equity Securities by the Issuer and Affiliated Purchasers	90
Item 16F. Change in Registrant's Certifying Accountant	91
Item 16G. Corporate Governance	91
Item 16H. Mine Safety Disclosure	91
PART III	F-1
Item 17. Financial Statements	F-1
Item 18. Financial Statements	F-1
Item 19. Exhibits	92

General Matters

In this Annual Report on Form 20-F (“Annual Report”), unless the context indicates otherwise, references to “NIS” are to the legal currency of Israel, “U.S. dollars,” “\$” or “dollars” are to United States dollars, and the terms “we,” “us,” “our company,” “our,” and “Vascular Biogenics” refer to Vascular Biogenics Ltd.

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, statements about:

- the initiation, timing, progress and results of our preclinical and clinical trials, and our research and development programs;
- our expectations about the availability of data from our clinical trials;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our plans for future clinical trials;
- our ability to manufacture our product candidates in sufficient quantities for clinical trials;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization of our product candidates, if approved;
- potential advantages of our product candidates;
- the pricing and reimbursement of our product candidates, if approved;
- our ability to develop and commercialize additional product candidates based on our platform technologies;
- our business strategy;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope and duration of protection we are able to establish and maintain for intellectual property rights covering our product candidates 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 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 the sections “Item 3. Key Information-D. Risk Factors,” “Item 5. Operating and Financial Review and Prospectus” 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.

The audited financial statements for the years ended December 31, 2020, 2019 and 2018 in this Annual Report have been prepared in accordance in accordance with U.S. GAAP.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. Selected Financial Data

The following table summarizes our financial data. We have derived the summary statements of operations data for the years ended December 31, 2020, 2019, and 2018, and the statements of financial position data as of December 31, 2020 and 2019 from our audited financial statements included elsewhere in this Annual Report.

The summary of our financial data set forth below should be read together with our audited financial statements and the related notes, as well as the section entitled “Item 5. Operating and Financial Review and Prospects,” included elsewhere in this Annual Report.

We have not included financial information for the years ended and as of December 31, 2017 and 2016 as such information cannot be provided on a restated U.S. GAAP basis without unreasonable effort or expense.

(in thousands, except share and per-share data)	2020	2019	2018
Statements of operations data:			
Revenues	\$ 922	\$ 562	\$ 585
Cost of revenues	(394)	(222)	(255)
Gross Profit	\$ 528	\$ 340	\$ 330
Research and development expenses, net	\$ 19,656	\$ 14,714	\$ 15,178
Marketing expenses	-	-	397
General and administrative expenses	5,355	5,708	6,000
Operating loss	24,483	20,082	21,245
Financial income	(363)	(870)	(908)
Financial expenses	105	184	159
Financial (income) expenses, net	(258)	(686)	(749)
Other comprehensive loss (income)			
Comprehensive loss	24,225	\$ 19,396	\$ 20,496
Loss per ordinary share, basic and diluted	0.55	\$ 0.54	\$ 0.62
Weighted average ordinary shares outstanding, basic and diluted	43,668,155	35,881,256	32,969,094
	December 31,		
	2020	2019	2018
	(in thousands)		
Statements of financial position data:			
Cash and cash equivalents and short-term bank deposits	\$ 30,807	\$ 37,042	\$ 50,482
Total assets	41,706	49,005	60,678
Total liabilities	10,789	12,982	7,515
Ordinary shares	108	73	73
Total shareholders' equity	30,917	36,023	53,163

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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. 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 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 a 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 \$24.2 million, \$19.4 million and \$20.5 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of \$232.2 million.

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 completed only a single pivotal clinical trial for our product candidates and it will be a few years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our product candidates 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 and preclinical and clinical development of our product candidates;
- expand the scope of our current clinical trials for our product candidates;
- initiate additional preclinical, clinical or other studies for our product candidates;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- further develop the manufacturing process for our product candidates;
- operate and possibly expand our new, commercial scale manufacturing facility;
- change or add additional manufacturers or suppliers;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;

[Table of Contents](#)

- make milestone or other payments under any in-license or other intellectual property related agreements, including our agreement with Tel Hashomer-Medical Research, Infrastructure and Services Ltd. and our license from Janssen Vaccines & Prevention B.V., or Janssen (formerly known as Crucell Holland B.V.), and any other 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; 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 our product candidates. 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 and preclinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;
- developing a sustainable, scalable, reproducible, and transferable manufacturing process for our product candidates;
- 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 our product candidates, if approved;
- and/or successfully establishing, validating and operating our own manufacturing facilities to produce our products in amount and quality, to support clinical development and the market demand for our product candidates, if approved, as well as passing inspections by health authorities, such as the Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, and obtaining approval for our manufacturing facility and product;
- launching and commercializing any product candidates 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 candidates that receive regulatory approval as 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 is 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 products, we may not become profitable and may need to obtain additional funding to continue operations.

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.

We are currently advancing VB-111 for solid cancer indications. We intend to advance this current clinical product candidate through clinical development and other product candidates through preclinical and clinical development. Developing pharmaceutical products is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates in clinical trials.

As of December 31, 2020, our cash and cash equivalents and short-term bank deposits were \$30.8 million. As of March 15, 2021, we estimate that the balance of cash, cash equivalents and short-term bank deposits at December 31, 2020 together with the funds received from the exercise of warrants, the share purchases by Aspire Capital LLC and the share sales on the ATM plan will be sufficient to fund our operations into the fourth quarter of 2022. However, our operating plan may change as a result of many factors currently unknown to us, 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, we might require additional capital to obtain regulatory approval for our product candidates, and to commercialize any that receive regulatory approval. Raising funds in the current economic environment may present additional challenges. Global health concerns resulting from the outbreak of the coronavirus in China and worldwide 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 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 our product candidates. 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 otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or product candidates 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 one or more of our research or development programs or the commercialization of any product candidates, and we may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired.

We have received and may continue to receive Israeli governmental grants to assist in the funding of our research and development activities. If we lose our funding from these research and development grants, we may encounter difficulties in the funding of future research and development projects and implementing technological improvements, which would harm our operating results.

Through December 31, 2020 we had received an aggregate of \$28.8 million in the form of grants from the Israeli Office of the Chief Scientist, or OCS, which has later transformed to the Israeli Innovation Authority, or IIA. The requirements and restrictions for such grants are found in the Israel Encouragement of Research and Development in Industries, or the Research Law. Under 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. We developed both of our platform technologies, at least in part, with funds from these grants, and accordingly we would be obligated to pay these royalties on sales of any of our product candidates that achieve regulatory approval. The maximum aggregate royalties paid generally cannot exceed 100% of the grants made to us, plus annual interest equal to the 12-month LIBOR applicable to dollar deposits, as published on the first business day of each calendar year. As of December 31, 2020, the balance of the principal and interest in respect of our commitments for future payments to the IIA totaled approximately \$36.0 million. To date, we have paid the IIA in relation to our licenses agreement royalties of approximately \$0.5 million. As part of funding our current and planned product development activities, we submitted follow-up grant application.

These grants have funded some of our personnel, development activities with subcontractors and other research and development costs and expenses. However, if these awards are not funded in their entirety or if new grants are not awarded in the future, due to, for example, IIA budget constraints or governmental policy decisions, our ability to fund future research and development and implement technological improvements would be impaired, which would negatively impact our ability to develop our product candidates.

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

Our research and development efforts have been financed, in part, through the grants that we have received from the IIA. We, therefore, must comply with the requirements of the Research Law.

Under the Research Law, we are required to manufacture the major portion of each of our products 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. Even if we do receive approval to manufacture products 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 products or technologies. See “Item 5. Operating and Financial Review and Prospects-Financial Overview-Research and Development Expenses” 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. 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, 2020, 2019 and, 2018, we recorded grants totaling \$1.5 million, \$2.7 million, and \$2.0 million from the IIA, respectively. The grants represented an approximately 7%, 15%, and 11% respectively, of our gross research and development expenditures for the years ended December 31, 2020, 2019 and, 2018. 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.

Recent at-the-market sales of our ordinary shares may not have been made in compliance with all applicable securities laws, which could expose us to potential liabilities, including potential rescission rights.

In January and February 2021, we sold approximately \$3.5 million of our ordinary shares pursuant to our existing Equity Distribution Agreement with Oppenheimer & Co., Inc. Those sales were made in an “at the market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, pursuant to our effective shelf registration statement on Form F-3 (File No. 333-251821). However, we inadvertently failed to file a prospectus supplement specifying details regarding such sales. This may have constituted a violation of Section 5 of the Securities Act and may give rise to liability under Section 12 of the Securities Act (which generally provides a rescission remedy for offers and sales of securities in violation of Section 5) as well as potential liability under the anti-fraud provisions of federal and state securities laws and state rescission laws.

In such event, anyone who acquired such ordinary shares would have a right to rescind the purchase. If all the shareholders who acquired ordinary shares demanded rescission, the maximum we would be obligated to repay would be approximately \$3.5 million, plus interest. Out of the \$3.5 million, there was an identified buyer of \$1.9 million. That buyer has agreed to waive his rescission right and signed a respective waiver. The Securities Act generally requires that any claim brought for a violation of Section 5 of the Securities Act be brought within one year of the violation. Additionally, if it is determined that such sales did in fact violate the Securities Act, we may become subject to fines and penalties imposed by the SEC and state securities agencies.

Risks Related to the Discovery and Development of Our Product Candidates

We have planned on the future success of our lead product candidate, VB-111, that missed the primary endpoints in the Phase 3 study in rGBM. We continue to advance VB-111 for ovarian cancer and other indications. Any failure to successfully develop, obtain regulatory approval for and commercialize VB-111 for cancer 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 invested a significant portion of our efforts and financial resources in the development of VB-111 for rGBM and VB-201 for psoriasis and ulcerative colitis for which we have completed clinical trials in which they did not meet their primary endpoints. Our ability to generate product revenue from our product candidates depends heavily on the successful development and commercialization of our product candidates, which, in turn, depends on several factors, including the following:

- our ability to continue and support the VTS platform technology and its lead candidate VB-111;
- successfully completing our ongoing and future trials of VB-111 or other product candidates;
- our ability to raise additional funding sufficient to conduct future clinical trials;

- demonstrating that VB-111 for cancer indications or other product candidates is safe and effective at a sufficient level of statistical or clinical significance and otherwise obtaining marketing approvals from regulatory authorities;
- operating our facility for the manufacture of commercial quantities of our product candidates, if approved;
- manufacturing our product candidates 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 current good manufacturing practices, or cGMP, and which will ensure the supply of our product candidates to the clinical development and commercial use, if approved;
- establishing successful sales and marketing arrangements for our products, if approved;
- maintaining an acceptable safety and efficacy profile for our products;
- the availability of coverage and reimbursement to patients from healthcare payors for our products, if approved; and
- other risks described in these “Risk Factors.”

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

We have concentrated our product research and development efforts on our three distinct platform technologies, and our future success depends on the successful development of these technologies. We could experience development problems in the future related to our technologies, 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 products on a timely or profitable basis, if at all.

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 novel product candidates 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.

Regulatory requirements governing pharmaceutical products have changed frequently and may continue to change in the future. Also, before a clinical trial can begin at an institution funded by the U.S. National Institutes of Health, or the NIH, that institution’s institutional review board, or IRB, and its Institutional Biosafety Committee will have to review the proposed clinical trial to assess the safety of the trial. 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 of our product candidates.

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 these treatment candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, 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 candidates. 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 candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates 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 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.

[Table of Contents](#)

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, VB-111 for ovarian cancer is intended for a rare disorder 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.

Additionally, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things pandemics. For example, in December 2019, an outbreak of a novel strain of coronavirus, or the SARS-CoV-2 coronavirus, which causes COVID-19, had ripple effects to businesses around the world, negatively impacted activity and operations, including extended shutdowns of certain businesses, in many countries, including the USA, European countries and Israel, where our operations are. The list of countries and regions affected by the coronavirus outbreak is constantly changing and our clinical trial sites may be located in regions currently being afflicted by the COVID-19 pandemic. Some factors from the coronavirus outbreak that we believe may adversely affect enrollment in our trials include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of infectious disease physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;
- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our trials; and
- employee furlough days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with the virus or could continue to spread to additional countries, each of which may further adversely impact our clinical trials. The global outbreak of the SARS-CoV-2 coronavirus continues to evolve and the conduct of our trials may continue to be adversely affected, despite efforts to mitigate this impact.

For more information on the extent that the COVID-19 pandemic has impacted our development programs to date, please refer to the related section in the Overview part.

The COVID-19 pandemic could also interrupt the business of our subcontractors, vendors and external laboratories, in ways and to an extent, that we cannot foresee yet.

We plan to seek initial marketing approval in Europe 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 contract research organizations, or CROs, 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 as planned, 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 candidates 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.

We are currently in Phase 3 clinical trial for VB-111 for ovarian cancer and expect to support two Sponsor-Investigator trials, one for rGBM and the other for GI tumors in combination with an immune-oncology drug. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates 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. 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 such as ovarian cancer;
- 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 good clinical practices, or GCP, or applicable regulatory requirements in other countries;
- delays in the testing, validation, manufacturing and delivery of our product candidates 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; or
- discontinuation or other hurdles in the expected Sponsor-Investigator trials, which are conducted by academic and other investigational third parties and are not controlled by us.

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 candidates, 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 candidates 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 our product candidates, we may:

- fail to obtain, or be delayed in obtaining, marketing approval for our product candidates;
- 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 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 in the form of a risk evaluation and mitigation strategy, or 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 candidates and impair our ability to commercialize our product candidates.

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

Treatment with our product candidates may cause side effects or adverse events. In addition, since our product candidates are in some cases 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 adverse events that have not yet been predicted. 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 candidates or, if approved, could negatively impact the market acceptance of such products.

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. 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 clinical trials may not be sufficiently robust to support the submission for marketing approval for our product candidates. Before we submit our product candidates 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 may require us to conduct additional clinical trials, possibly involving a larger sample size or a different clinical trial design, particularly if the FDA does not find the results from our completed clinical trials to be sufficiently persuasive to support a Biologics License Application, or BLA, or a New Drug Application, or NDA. For example, because the dose we used in our Phase 2 trial was limited by our production capacity, the dose of VB-111 that we intend to use in our Phase 3 registration enabling trial may not be the maximum efficacious dose. The FDA might require data on higher doses of VB-111, this will likely delay development. The FDA may also require that we conduct a longer follow-up period of subjects treated with our product candidates prior to accepting our BLA or NDA.

It is possible that the FDA or the EMA may not consider the results of our clinical trials to be sufficient for approval of our product candidates for their 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 BLA or NDA and Marketing Authorization Application, which is the equivalent of a 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 candidates demonstrate 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. 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.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

If a drug is intended for the treatment of a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for this disease or condition, the drug sponsor may apply for FDA fast track designation. If fast track designation is obtained, the FDA may initiate review of sections of an NDA or BLA, before the application is complete. This “rolling review” is available if the applicant provides, and the FDA approves, a schedule for submission of the individual sections of the application.

We have received fast track designation from the FDA for VB-111 for prolongation of survival in patients with glioblastoma that has recurred following treatment with temozolomide, a chemotherapeutic agent commonly used to treat newly diagnosed glioblastoma, and radiation. We may seek fast track designation for other product candidates and other indications. Even though we have received fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Our fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures or that we will ultimately obtain regulatory approval of VB-111.

Even though we have obtained orphan drug designation for VB-111 for treatment of malignant glioma in the United States and glioma in Europe, and for the treatment of ovarian cancer in Europe, we may not be able to obtain orphan drug exclusivity for this drug or for any of our other product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. For VB-111, we have obtained orphan drug designation from the FDA for the treatment of malignant glioma and the European Commission for the treatment of glioma and ovarian cancer, and we may seek orphan drug designation for other drug candidates.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug for the same use or indication for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Even if we obtain regulatory approval for a product candidate, our products 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 candidates, 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 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 manufacturers and their 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 adherence to commitments made in the BLA or NDA 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 of our product candidates, 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 NDA or supplements to a BLA or NDA submitted by us for other indications or new drug products;
- 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 candidates 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 drug and biologics candidates. Moreover, the product candidates that are likely to result from our development programs are based on new technologies that have not been extensively tested in humans. The regulatory requirements governing these types of product candidates may be less well defined or more rigorous than for conventional products. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals of any products that we develop. 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 candidates.

In addition to the level of commercial success of our product candidates, 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 technologies to identify or discover additional product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our three platform technologies. 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.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs. 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. In addition, we may pursue further clinical development of VB-111 for thyroid cancer or other indications with a strategic partner.

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 product candidates that we develop and commercialize on our own, we will remain responsible for ensuring that each of our Investigational New Drug, or IND, enabling studies and clinical trials are conducted in accordance with the study plan and protocols.

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 candidates 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 contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. 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 candidates. Each supplier may require licenses to manufacture components of our product candidates or to utilize certain processes for the manufacture of our product candidates. 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 candidates, 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. 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 candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA or NDA, as applicable, on a timely basis and must adhere to the FDA's good laboratory practices, or GLP, and cGMP regulations enforced by the FDA through its facilities inspection program. We and our contract manufacturer for VB-111 have not produced a commercially approved product based on viral vectors and therefore have not yet obtained the requisite FDA approvals to do so. Our facilities and controls and 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 candidates 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 candidates 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 products 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 drug product or biologic product, or revocation of a pre-existing approval.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA or NDA supplement which could result in further delay. The regulatory agencies may also require additional 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.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products 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 may be delayed or we could lose potential revenue.

We expect 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 expect 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 GCPs 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 GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, 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 GCPs. In addition, our clinical trials will require a sufficient number of test subjects to evaluate the safety and effectiveness of our product candidates. Recruitment may be challenging in the event of rare diseases and may 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 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 candidates 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 candidates 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 candidates or commercialization of our product candidates, 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 candidates, 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 our product candidates.

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 Commercialization of Our Product Candidates

We intend to fully rely or partially rely on third-party manufacturers to produce commercial quantities of any of our product candidates that receives 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 candidates at commercial levels and may not pass regulatory inspections or achieve the necessary regulatory approvals or produce our product candidates at the quality, quantities, locations and timing needed to support commercialization.

We have not yet secured manufacturing capabilities for commercial quantities of our product candidates to support world-wide commercialization of our product candidates. Although we intend to partially rely on third-party manufacturers for commercialization, we have only entered into agreements with such manufacturers to assist in the scaling up of the manufacturing process of VB-111. We may be unable to negotiate binding agreements with the manufacturers to support our commercialization activities on commercially reasonable terms, which agreements will further be required to comply with the restrictions imposed under the Research Law.

We may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds. Although we have established a site in which we are planning to apply a commercial scale manufacturing, the available capacity to manufacture our product candidates on a commercial scale is still limited. In addition, our product candidates are novel, and no manufacturer currently has the experience or ability to produce our product candidates at commercial levels. If we are unable to produce or engage manufacturing partners to produce our product candidates on a larger scale on reasonable terms, our commercialization efforts will be harmed.

Even if we timely complete the development of a manufacturing process and successfully transfer it to the third-party manufacturers of our product candidates, if we or such third-party manufacturers are unable to produce the necessary quantities of our product candidates, or in compliance with cGMP or with pertinent regulatory requirements, and within our planned time frame and cost parameters, the development and sales of our product candidates, if approved, may be impaired.

In addition, any significant disruption in our supplier relationships could harm our business. We source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There are a small number of suppliers, and in some cases a single supplier for certain key materials that are used to manufacture our product candidates. Such suppliers may not sell these key materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these key materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these key materials.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell any of our product candidates that obtain regulatory approval, we may be unable to generate any revenue.

We have no experience selling and marketing our product candidates or any other products. To successfully commercialize any products that may result from our development programs and obtain regulatory approval, we will need to develop these capabilities, either on our own or with others. We may seek to enter into collaborations with other entities to utilize their marketing and distribution capabilities, but we may be unable to do so on favorable terms, if at all. If any future collaborative partners do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without sufficient internal capability or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies or successfully commercialize any of our product candidates.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which could impair our ability to successfully commercialize our product candidates.

We are engaged in pharmaceutical development, which is a rapidly changing field. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

Many of our potential competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our potential competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than us. Additionally, technologies developed by others may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

In particular, VB-111 may face competition from currently approved drugs and drug candidates under development by others to treat rGBM or ovarian cancer. In May 2009, the FDA granted accelerated approval to bevacizumab (Avastin[®]), which is an angiogenesis inhibitor, to treat patients with rGBM at progression after standard first-line therapy. Bevacizumab also received FDA approval for platinum-resistant ovarian cancer in 2014, and for newly diagnosed patients after their initial surgery in 2018. In addition to bevacizumab, a number of companies are conducting late-stage clinical trials to test targeted drugs focused on angiogenesis inhibition for the treatment of ovarian cancer, including, among others, Amgen's trebananib, Boehringer Ingelheim's nintedanib, AstraZeneca's cediranib, Novartis's Votrient, HengRui Medicine's apatinib and Mereo BioPharma's navicixizumab. The expansion of PARP inhibitors (such as olaparib, niraparib and veliparib) for ovarian cancer, and clinical studies evaluating the potential use of checkpoint inhibitors, antibody-drug conjugates, bispecific Abs, GAS6/AXL inhibitors, WEE1 inhibitors, CDK4/6 inhibitors or Tumor Treating Fields medical device for ovarian cancer may also affect the prior lines of therapy, or the segment of patient population who will seek treatment with VB-111.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from biosimilars. In the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or biosimilar, to or "interchangeable" with an FDA-approved biological product. This pathway could allow competitors to reference data from biological products already approved after 12 years from the time of approval. In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data from biological products already approved, but will not be able to market a biosimilar until ten years after the time of approval. This 10-year period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired.

In addition, although VB-111 has been granted orphan drug status by the FDA and EMA for a specified indication, there are limitations to the exclusivity. In the United States, the exclusivity period for orphan drugs is seven years, while pediatric exclusivity adds six months to any existing patents or exclusivity periods. In Europe, orphan drugs may be able to obtain 10 years of marketing exclusivity and up to an additional two years on the basis of qualifying pediatric studies. However, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria. Additionally, a marketing authorization holder may lose its orphan exclusivity if it consents to a second orphan drug application or cannot supply enough drug. Orphan drug exclusivity also can be lost when a second applicant demonstrates its drug is “clinically superior” to the original orphan drug.

Finally, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity or scope of patents relating to other parties’ products. The availability of other parties’ products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

Since some of our product candidates are aimed for rare diseases, loss of exclusivity or competition as described above may be very significant in light of the limited size of the relevant market.

The commercial success of any current or future product candidate, if approved, will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even if we obtain the requisite regulatory approvals, the commercial success of our product candidates will depend in part on the medical community, patients, and third-party payors accepting our product candidates as medically useful, cost-effective, and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of these product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product’s approved labeling;
- the prevalence and severity of any side effects resulting from the procedure by which our product candidates are administered;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by conventional technologies.

A variety of risks associated with international operations could hurt our business.

If any of our product candidates are approved for commercialization, it is our current intention to market them on a worldwide basis, either alone or in collaboration with others. In addition, we conduct development activities in various jurisdictions throughout the world. We expect that we will be subject to additional risks related to engaging in international operations, including:

- different regulatory requirements for approval of drugs and biologics in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States and Israel;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, global outbreaks of disease, or natural disasters including earthquakes, typhoons, floods and fires.

We have not undertaken a systematic analysis of the potential consequences to our business as a result of any such natural disaster, public health crisis or pandemic diseases and do not have an applicable recovery plan in place. In addition, if any of our third-party contract manufacturers are affected by natural disasters, such as earthquakes, power shortages or outages, floods, wildfire, public health crises, such as pandemics and epidemics terrorism or other events outside of our control, our business and operating results could suffer. For example, in December 2019, a strain of coronavirus was reported to have surfaced in Wuhan, China. At this point, the extent to which the coronavirus may impact our business and operating results is uncertain. We carry only limited business interruption insurance that would compensate us for actual losses from interruption of our business that may occur and any losses or damages incurred by us in excess of insured amounts could cause our business to materially suffer.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for any of our product candidates that are approved could limit our ability to market those products and compromise our ability to generate revenue.

The availability of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both in the U.S. and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries.

The intended use of a drug product by a physician can also affect pricing. For example, CMS could initiate a National Coverage Determination administrative procedure, by which the agency determines which uses of a therapeutic product would and would not be reimbursable under Medicare. This determination process can be lengthy, thereby creating a long period during which the future reimbursement for a particular product may be uncertain.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries is likely to put pressure on the pricing and usage of any of our product candidates that are approved for marketing. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs, resulting in legislation and reforms may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

The prescription for or promotion of off-label uses of our products by physicians could adversely affect our business.

Any regulatory approval of our products is limited to those specific diseases and indications for which our products have been deemed safe and effective by the FDA or similar authorities in other jurisdictions. In addition, any new indication for an approved product also requires regulatory approval. If we produce an approved therapeutic product, we will rely on physicians to prescribe and administer it as we have directed and for the indications described on the labeling. It is not, however, uncommon for physicians to prescribe medication for unapproved, or “off-label,” uses or in a manner that is inconsistent with the manufacturer’s directions. To the extent such off-label uses and departures from our administration directions become pervasive and produce results such as reduced efficacy or other adverse effects, the reputation of our products in the marketplace may suffer. In addition, off-label uses may cause a decline in our revenue or potential revenue, to the extent that there is a difference between the prices of our product for different indications.

Furthermore, while physicians may choose to prescribe our drugs for off-label uses, our ability to promote the products is limited to those indications that are specifically approved by the FDA or other regulators. Although regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies with respect to off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in the FDA’s refusal to approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution.

Due to the small target patient populations for some of our product candidates, we face uncertainty related to pricing and reimbursement for these product candidates.

Some of our target patient populations for our initial product candidates are relatively small, as a result of which the pricing and reimbursement of our product candidates, if approved, must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates will be adversely affected. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products.

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 principal members of our executive team listed under “Management” in this report, 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 executive officers, 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. 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. 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 commercialization 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 will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of March 1, 2020, we had 38 employees. As we mature and undertake the activities required to advance our product candidates into later stage clinical development and to operate as a public company, we expect to expand our full-time employee base and to hire more consultants and contractors. 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 to managing these growth activities. We may not be able to effectively manage the expansion of 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. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, 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 commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future 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.

Pandemics such as the coronavirus could have an adverse impact on our developmental programs and our financial condition.

In December 2019, an outbreak of a novel strain of coronavirus, or the SARS-CoV-2 coronavirus, which results in COVID-19, had ripple effects to businesses around the world, negatively impacted activity and operations, including extended shutdowns of certain businesses, in many countries, including the USA, European countries and Israel, where our operations are. The list of countries and regions affected by the coronavirus outbreak is constantly changing and our clinical trial sites may be located in regions currently being afflicted by the COVID-19 pandemic. Any outbreak of contagious diseases, or other adverse public health developments, could have a material and adverse effect on our business operations. These could include disruptions or restrictions on our ability to travel, pursue partnerships and other business transactions, conduct clinical trials, make shipments of biologic materials, as well as be impacted by the temporary closure of the facilities of suppliers and clinical trial sites. Any disruption of suppliers, clinical trial sites or access to patients would likely impact our clinical trial enrollment progress and rates as well as our ability to access capital through the financial markets. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

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 candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, 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 candidates. There is a risk that our product candidates 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 our product candidates;
- decreased demand for our product candidates, 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 of \$5.0 million per occurrence and \$5.0 million aggregate limit, with extension to \$10.0 million for the Phase 3 study in rGBM and for the Phase 3 study in ovarian cancer. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; 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 candidates, 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.

If our existing or future manufacturing facility is damaged or destroyed, or production at any of those facilities is otherwise interrupted, our business and prospects would be negatively affected.

We have a manufacturing facility for commercial scale production. If our existing or future manufacturing facilities, or the equipment in it, is damaged or destroyed, we likely would not be able to quickly or inexpensively replace our manufacturing capacity and possibly would not be able to replace it at all. Any new facility needed to replace our existing or future manufacturing facility would need to comply with the necessary regulatory requirements, and be tailored to our manufacturing requirements and processes. We would need FDA approval before using any product candidates manufactured at a new facility in clinical trials or selling any products that are ultimately approved. Such an event could delay our clinical trials or, if any of our product candidates are approved by the FDA, reduce or eliminate our product sales.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of 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.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If our shipping capabilities become unavailable due to an accident, an act of terrorism, a labor strike or other similar event, our supply, production and distribution processes could be disrupted.

Some of our raw materials for the manufacturing of VB-111, and VB-111 itself, must be transported at a temperature controlled cold chain at temperatures varying between -4 degrees Celsius to -70 degrees Celsius (25 to -94 degrees Fahrenheit) to ensure their quality and vitality. Not all shipping or distribution channels are equipped to transport at these temperatures. If any of our shipping or distribution channels become inaccessible because of a serious accident, an act of terrorism, global health pandemic, a labor strike or other similar event, we may experience disruptions in our continued supply of raw materials, delays in our production process or a reduction in our ability to distribute our therapeutics to our customers.

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 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. 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 Securities and Exchange Commission, or SEC, and The NASDAQ Global Market have imposed various requirements on public companies. 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 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, as of December 31, 2019, we were no longer an “emerging growth company,” as defined in the JOBS Act, and are now required to comply with additional disclosure and reporting requirements. 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. Presently we qualify as a non-accelerated filer, meaning we have a public float of less than \$75 million measured as of the last business day of our most recently completed second fiscal quarter, and thus remain exempt from Section 404(b) of the Sarbanes-Oxley Act, which generally requires public companies (including foreign private issuers) to provide an independent auditor attestation of the effectiveness of their internal controls. However, in the event that we become an accelerated filer, we will incur additional costs in connection with compliance with Section 404(b) of the Sarbanes-Oxley Act.

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. For example, the average exchange rate of the dollar against the NIS decreased materially in 2020, and decreases moderately in 2019 and in 2018. 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.

Risks Related to Our Intellectual Property

We depend on our license agreement with Janssen Vaccines & Prevention B.V. and if we cannot meet requirements under such license agreement, we could lose the rights to our products, which could have a material adverse effect on our business.

VB-111 incorporates an adenoviral vector as the delivery vehicle, which its manufacturing is based on our rights under a license agreement with Janssen Vaccines & Prevention B.V. If we fail to meet our obligations under this license agreement, including various diligence, milestone payment, royalty and other obligations, Janssen Vaccines & Prevention B.V. has the right to terminate our license, and upon the effective date of such termination, our right to use the licensed technology would terminate. We may enter into additional agreements in the future with Janssen Vaccines & Prevention B.V. that may impose similar obligations on us. While we would expect to exercise all rights and remedies available to us, including attempting to cure any breach by us, and otherwise seek to preserve our rights under the patents and other technology licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the license agreement could result in our loss of rights and may lead to a complete termination of our product development and any commercialization efforts for the applicable product candidates since there are currently no significant similar alternatives on the market.

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.

If the patent applications we hold or have in-licensed 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. Since 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.

Recent 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 (the Leahy-Smith Act) enacted in 2013 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 with the Act, in particular, the Inter Partes Review (IPR) proceedings. It remains to be seen what impact the Leahy-Smith Act will have on the operation of our business. However, the Act and 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 to 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.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant may contend that the patent covering our product candidate is invalid, unenforceable or fails to cover the product candidate or the infringing product. In patent litigation in the United States, defendants commonly allege that asserted patent claims are invalid and unenforceable. Grounds for a validity challenge could be an alleged failure to meet one or more of several statutory requirements, including lack of novelty, obviousness, lack of written description, indefiniteness and non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation, amendments to our patent claims or statements being made on the record such that our claims may no longer be construed to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity, unenforceability or non-infringement, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our ordinary shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

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 recently 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.

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.

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;

- any delay in filing an IND or BLA for any of our product candidates 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 our product candidates 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 to scale up our manufacturing capabilities (including in Israel), inability to obtain adequate product supply for our product candidates 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 financial projections we may provide to the public;
- failure to meet or exceed the financial expectations of the investment community;
- 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 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;
- 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 the NASDAQ Global Market, 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, 2020, to the best of our information, our executive officers, directors, five percent shareholders and their affiliates beneficially owned approximately 30.5% of our voting shares. Therefore, these shareholders have the ability to control 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.

Our ordinary shares are subject to substantial dilution in their book value.

As of December 31, 2020, options, RSUs and warrants to purchase 23,264,072 ordinary shares at a weighted average exercise price of \$2.38 per share were outstanding. The exercise of any of these options and warrants would result in additional dilution.

Sales of a substantial number of our ordinary shares in the public market could cause our share price to fall.

If our existing shareholders sell, indicate an intention to sell or the market perceives that they intend to sell, substantial amounts of our ordinary shares in the public market, the market price of our ordinary shares could decline significantly. As of December 31, 2020, we had outstanding a total of 48,187,463 ordinary shares. Substantially all of the shares are available for sale in the public market.

As of December 31, 2020, 14,678,180 ordinary shares are held by directors, executive officers and other affiliates (holders of more than 10% of the Company's share capital) and are subject to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

In addition, as of March 1, 2021, an aggregate of 15,009,831 ordinary shares that are either subject to outstanding options, reserved for future issuance under our 2014 Plan or subject to outstanding warrants will or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our ordinary shares could decline.

Future sales and issuances of our ordinary shares or rights to purchase ordinary shares, including pursuant to our equity incentive plans, 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. If we sell ordinary shares, convertible securities or other equity securities in more than one transaction, 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.

Pursuant to our Employee Share Ownership and Option Plan (2014), or the 2014 Plan, our management is authorized to grant share options and other equity-based awards to our employees, directors and consultants. Currently, we plan to register the increased number of shares available for issuance under the 2014 Plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our shareholders may experience additional dilution, which could cause our share price to fall.

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. For example, the price of our ordinary shares, which reached its high record of \$17.02 per share at the close of the trading on January 27, 2015, decreased as low as \$2.8 per share at the close of the trading on February 1, 2016 a drop of about 84%. In addition, the price of our ordinary shares, which was \$6.80 per share at the close of the trading on March 7, 2018, decreased to \$2.65 per share at the close of the trading on March 8, 2018 and to its low record of \$0.6 per share at the close of the trading on December 21, 2018. If we face 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 cease publishing reports about us or our business.

Risks Related to Our Incorporation and Operations in Israel

We are a “foreign private issuer” and intend to follow certain home country corporate governance practices, and our shareholders may not have the same protections afforded to shareholders of companies that are subject to all NASDAQ corporate governance requirements. Additionally, we cannot be certain if the reduced disclosure requirements applicable to our status as a foreign private issuer, will make our ordinary shares less attractive to investors.

As a foreign private issuer, we are permitted, and intend, to follow certain home country corporate governance practices instead of those otherwise required under the NASDAQ Stock Market for domestic U.S. issuers. For instance, we intend to follow home country practice in Israel with regard to the quorum requirement for shareholder meetings. As permitted under the Israeli Companies Law, 5759-1999, or the Companies Law, our articles of association provide that the quorum for any meeting of shareholders shall be the presence of at least two shareholders present in person, by proxy or by a voting instrument, who hold at least 25% of the voting power of our shares instead of the 33 1/3% of the issued share capital requirement. We may in the future elect to follow home country practices in Israel (and consequently avoid the requirements that would otherwise apply to a U.S. company listed on The NASDAQ Global Market) with regard to other matters, as well, such as the formation of compensation, nominating and governance committees, separate executive sessions of independent directors and non-management directors and the requirement to obtain shareholder approval for certain dilutive events (such as for the establishment or amendment of certain equity-based compensation plans, issuances that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company). Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on The NASDAQ Global Market may provide less protection to you than what is accorded to investors under the NASDAQ Stock Market rules applicable to domestic U.S. issuers. See “Item 16G. Corporate Governance” for more information.

In addition, as a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements, including with regards to compensation of executive officers and our officers, directors and principal shareholders we are exempt from the reporting and the short-swing profit recovery provisions contained in Section 16 of the Exchange Act. We are also permitted to disclose limited compensation information for our executive officers on an individual basis and we are generally exempt from filing quarterly reports with the SEC under the Exchange Act. A recent amendment to regulations under the Israeli Companies Law requires us to disclose in the notice for our annual meeting of shareholders, the annual compensation of our five most highly compensated officers on an individual, rather than aggregate, basis. However, this disclosure is not as extensive as that required of a U.S. domestic issuer.

Further, we are not required under the Exchange Act to file annual and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act. Moreover, we are not required to comply with Regulation FD, which restricts the selective disclosure of material nonpublic information to, among others, broker-dealers and holders of a company’s securities under circumstances in which it is reasonably foreseeable that the holder will trade in the company’s securities on the basis of the information. These exemptions and leniencies reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic issuer.

We would lose our foreign private issuer status if a majority of our directors or executive officers are U.S. citizens or residents and we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. Although we have elected to comply with certain U.S. regulatory provisions, our loss of foreign private issuer status would make such provisions mandatory. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic reporting company may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic reporting company forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We may be required to modify certain of our policies to comply with accepted governance practices associated with U.S. domestic reporting companies. Such conversion and modifications will involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers.

We cannot predict if investors will find our ordinary shares less attractive because we may rely on these reduced requirements. 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.

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

We are incorporated under Israeli law and our offices and operations are located in the State of Israel. In addition, our key employees, officers and all but two 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.

Although Israel has entered into various agreements with Egypt, Jordan and the Palestinian Authority, there has been an increase in unrest and terrorist activity, which began in October 2000 and has continued with varying levels of severity. The establishment in 2006 of a government in the Palestinian Authority by representatives of the Hamas militant group has created additional unrest and uncertainty in the region. In 2006, a conflict between Israel and the Hezbollah in Lebanon resulted in thousands of rockets being fired from Lebanon up to 50 miles into Israel. Starting in December 2008, for approximately three weeks, Israel engaged in an armed conflict with Hamas in the Gaza Strip, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In November 2012, for approximately one week, Israel experienced a similar armed conflict, resulting in hundreds of rockets being fired from the Gaza Strip and disrupting most day-to-day civilian activity in southern Israel. Beginning in July 2014, for approximately seven weeks, Israel experienced additional armed conflict between Israel and Hamas, which included rocket strikes against civilian targets in various parts of Israel. If renewed, these hostilities may negatively affect business conditions in Israel. 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, since the end of 2010, 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. The civil unrest in Egypt, which borders Israel, resulted in the resignation of its president Hosni Mubarak, and to significant changes to the country's government. In Syria, also bordering Israel, a civil war is continuing to take place. 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.

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

As of March 1, 2021, we had 38 employees, all of whom were based in Israel. Some of our 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, including in connection with the 2006 conflict in Lebanon, and the December 2008, November 2012 and July-August 2014 conflicts with Hamas, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees related to military service or the absence for extended periods of one or more of our key employees for military service. Such disruption 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. See “Item 10E. Taxation-Israeli Tax Considerations and Government Programs-Law for the Encouragement of Capital Investments, 5719-1959.”

It may be difficult to enforce a U.S. judgment against us, our officers and directors and the Israeli experts named in this prospectus 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. All of our executive officers and all but two of our directors, and the Israeli experts named in this prospectus, 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.

Since 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 6. Directors, Senior Management and Employees-Approval of Related Party Transactions Under Israeli Law-Shareholders’ Duties.”

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 “Item 10B. 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, 2019 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. See “Item 10E. Taxation-Certain Material U.S. Federal Income Tax Considerations-Passive Foreign Investment Company Considerations.”

Since 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 had no revenue-producing operations until and including table year 2016. We believe that we were not a PFIC for our 2017, 2018, 2019 and 2020 taxable years. In addition, unless and until we generate sufficient revenue from active licensing and other non-passive sources and otherwise satisfy the asset test above, we might be treated as a PFIC in future taxable years.

Item 4. Information on the Company

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. Our service agent in the United States is located at c/o Puglisi and Associates, 850 Library Avenue, Suite 204, New Ark, Delaware 19711 and our telephone number is 972-8-9935000. Throughout this prospectus, we refer to various trademarks, service marks and trade names that we use in our business. The “Vascular Biogenics” design logo, “VBL Therapeutics,” “Vascular Targeting System,” “VTS,” “Lecinoxoids,” “VB-111,” “VB-201,” the “OVAL” design logo and other trademarks or service marks of Vascular Biogenics Ltd. appearing in this prospectus are the property of Vascular Biogenics Ltd. We have several other registered trademarks, service marks and pending applications relating to our products. Although we have omitted the “®” and trademark designations for such marks in this prospectus, all rights to such trademarks are nevertheless reserved. Other trademarks and service marks appearing in this prospectus are the property of their respective holders.

Capital Expenditures

For a discussion of our capital expenditures, see “Item 5. Operating and Financial Review and Prospects-Liquidity and Capital Resources.”

Business Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class treatments for areas of unmet need in cancer and immune/inflammatory indications. We have developed three platform technologies: a gene-therapy based technology for targeting newly formed blood vessels with focus on cancer, an antibody-based technology targeting MOSPD2 for immuno-oncology and anti-inflammatory applications, and the Lecinoxoids, a family of small-molecules for chronic immune-related indications.

Our main program in oncology is based on our proprietary Vascular Targeting System, or VTS, platform technology, which we believe will allow us to develop product candidates for multiple oncology indications. The VTS technology utilizes genetically targeted therapy to destroy newly formed, or angiogenic, blood vessels. By utilizing a viral vector as a delivery mechanism, the VTS platform can also lead to induction or enhancement of a localized anti-tumor immune response, thereby turning immunologically ‘cold’ tumors ‘hot’.

Our lead product candidate, VB-111 (ofranergene obadenovec), is a gene-based biologic that we are developing for solid tumor indications, and which we have advanced to programs for ovarian cancer, recurrent glioblastoma, or rGBM, an aggressive form of brain cancer, and thyroid cancer. We have obtained fast track designation for VB-111 in the United States for prolongation of survival in patients with glioblastoma that has recurred following treatment with standard chemotherapy and radiation. We have also received orphan drug designation for GBM in both the United States and Europe. VB-111 has also received an orphan designation for the treatment of ovarian cancer by the European Commission.

OVAL is our international Phase 3 randomized pivotal registration enabling clinical trial that compares a combination of VB-111 and paclitaxel to placebo plus paclitaxel, in patients with platinum-resistant ovarian cancer. The study is planned to enroll 400 patients. In March 2020, we announced the outcome of the planned interim analysis in the OVAL study. The OVAL independent Data Safety Monitoring Committee (DSMC) reviewed unblinded data and assessed CA-125 response, measured according to the GCIG criteria, in the first 60 enrolled subjects evaluable for CA-125 analysis. The DSMC confirmed that the study met the interim pre-specified efficacy criterion, of an absolute percentage advantage of 10% or higher CA-125 response rate for the VB-111 treatment arm, and recommended the study continue. The overall response rate in the first 60 randomized evaluable patients was 53%. Assuming a balanced randomization, the response rate in the treatment arm (VB-111 in addition to weekly paclitaxel) was 58% or higher. In patients who had post-dosing fever, which is a marker for VB-111 treatment, the response rate was 69%. Results of the interim analysis were published in a peer-review manuscript (Arend *et al.*, Gynecol Oncol. 2021).

The following analysis of the OVAL study was conducted in August 2020. The DSMC reviewed unblinded overall survival (OS) data of the first 100 enrolled subjects with a follow-up of at least 3 months. The committee also looked at response rate and safety information. The DSMC recommended that the study continue as planned. The primary endpoint of the OVAL Phase 3 study is OS.

In February 2021, we announced the results of a subsequent DSMC pre-planned review of the OVAL study. The committee, which reviewed unblinded data of about 200 patients, found no safety issues with the trial and recommended its continuation as planned. The next DSMC review in the OVAL study is expected in the third quarter of 2021. Our OVAL study is being conducted in collaboration with the GOG Foundation, Inc., a leading organization for research excellence in the field of gynecologic malignancies.

Final results from our Phase 1/2 clinical trial of VB-111 for recurrent platinum-resistant ovarian cancer were reported in June 2019 and published online in April 2020 (Arend *et al.*, Gynecol Oncol. 2020). Data demonstrated a median OS of 498 days in the VB-111 therapeutic-dose arm, versus 172.5 days in the low-dose arm (p=0.03). 58% of evaluable patients treated with the therapeutic dose of VB-111 had a GCIG CA-125 response. VB-111 activity signals were seen despite unfavorable prognostic characteristics (48% platinum refractory disease and 52% previous treatment with anti-angiogenics). There was a trend for favorable survival in patients who had CA-125 decrease >50% in the VB-111 therapeutic-dose arm (808 vs. 351 days; p=0.067) implicating CA-125 as a potentially valuable biomarker for response to VB-111. Post treatment fever was also associated with a signal for improved survival (808 vs. 479 days; p=0.27).

In a Phase 2 study for rGBM, patients who were primed with VB-111 monotherapy that was continued after progression with the addition of bevacizumab (Avastin[®]) showed significant survival (414 vs 223 days; HR 0.48; p=0.043) and progression free survival (PFS) advantage (90 vs 60 days; HR 0.36; p=0.032) compared to a cohort of patients that had limited exposure to VB-111 (Brenner *et al.*, Neuro Oncol. 2019). Radiographic responders to VB-111 exhibited specific imaging characteristics related to its mechanism of action. Survival advantage was also seen in comparison to historic controls, with the percentage of patients living more than one year doubling from 24% to 57%.

Our Phase 3 GLOBE study in rGBM compared upfront concomitant administration of VB-111, without priming, and bevacizumab to bevacizumab monotherapy. The study, which enrolled a total of 256 patients in the US, Canada and Israel was conducted under a special protocol assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA, with full endorsement by the Canadian Brain Tumor Consortium (CBTC). In this modified regimen, the treatment did not improve overall survival (OS) and PFS outcomes in rGBM. Study results (Cloughesy *et al.* Neuro Oncol. 2019) attribute the contradictory outcomes between the Phase 2 and Phase 3 trials as being related to the lack of VB-111 monotherapy priming in the GLOBE study, providing clinical, mechanistic and radiographic support for this hypothesis. Notably, GLOBE data show improved outcomes associated with a post VB-111 fever reaction, similar to outcomes from previous VB-111 studies, providing support that fever is a potential biomarker for better survival with VB-111, secondary to the drug's immunologic mechanism of action. No new safety concerns associated with VB-111 have been identified in the study. We do not think that results of the GLOBE study will necessarily have implications on the prospects for VB-111 in other regimens or tumor types.

On March 1, 2021, we announced that patient dosing has been initiated in a Phase 2 clinical trial investigating VB-111 for the treatment of rGBM. The new Phase 2 study, sponsored by Dana-Farber Cancer Institute in collaboration with a group of top neuro-oncology US medical centers, will investigate neo-adjuvant and adjuvant treatment with VB-111 in rGBM patients undergoing a second surgery.

VB-111 is also being studied in combination with nivolumab, an anti-PD1 immune checkpoint inhibitor, in the treatment of metastatic colorectal cancer. The study is being sponsored by the U.S. National Cancer Institute under a Cooperative Research and Development Agreement, or CRADA. The open label exploratory Phase 2 study will investigate if priming with VB-111 can drive immune cells into the tumor and turn the colorectal tumors from being immunologically "cold" to "hot." Enrollment in this clinical trial started in September 2020. A preliminary readout in this study is expected in the first half of 2021.

In February 2017, we reported full data from our exploratory Phase 2 study of VB-111 in recurrent, iodine-resistant differentiated thyroid cancer. The primary endpoint of the trial, defined as 6-month progression-free-survival (PFS-6) of 25%, was met with a dose response. Forty-seven percent of patients in the therapeutic-dose cohort reached PFS-6, versus 25% in the sub-therapeutic cohort, both groups meeting the primary endpoint. An overall survival benefit was seen, with a tail of more than 40% at 3.7 years for the therapeutic-dose cohort, similar to historical data for pazopanib (Votrient®), a tyrosine kinase inhibitor; however, most patients in the VB-111 study had tumors that previously had progressed on pazopanib or other kinase inhibitors.

Over 300 patients were exposed to VB-111 in completed clinical trials and it has been observed to be well-tolerated. In December 2015, we have been granted a US composition of matter patents that provides intellectual property protection for VB-111 in the US until October 2033 before any patent term extension.

We are also conducting two parallel drug development programs that are exploring the potential of MOSPD2, a protein that we identified as a key regulator of cell motility, as a therapeutic target for inflammatory diseases and cancer.

For inflammatory applications, we are developing classical antibodies that are designed to bind and block MOSPD2 on immune cells. Our data show that MOSPD2, which is predominantly expressed on the surface of human monocytes, is essential for their migration. By inhibiting this protein, we seek to block this migration of monocytes to sites of inflammation, and accordingly to reduce inflammation and tissue damage. We believe that antibodies targeting MOSPD2 have potential for treatment of various inflammatory indications, and are advancing our lead preclinical candidate VB-601 through IND-enabling studies. In September 2020, we announced the successful completion of a Type B pre-IND meeting with the FDA regarding our development plan for VB-601. Toxicology studies for VB-601 are currently underway. Submission of an IND for the clinical development of VB-601 is expected to occur in the first half of 2022.

For oncology applications, we are developing antibodies aimed to kill tumor cells, based on MOSPD2 as a target whose expression is induced in multiple tumors. We found that MOSPD2 was detected in the majority of cancerous organs, including colon, esophagus, liver and breast, where MOSPD2 seems to play a key role in cancer cell metastasis (Salem *et al.*, Int J. Cancer 2019). Given the specificity of MOSPD2 expression and its highly elevated expression in tumors, we believe MOSPD2 can serve as a novel target for immuno-oncology mediated therapy for cancer.

In October 2020, we announced that the European Patent Office (EPO) has granted Patents #3328408 and #3328401, which cover VBL's proprietary investigational anti-MOSPD2 monoclonal antibodies to treat inflammatory conditions and oncology conditions, respectively. The patents are expected to provide protection for VBL's MOSPD2 antibodies for inflammation and cancer, until at least July 2036.

We also have been conducting a program targeting anti-inflammatory diseases, based on the use of our Lecinoxoid platform technology. Lecinoxoids are a novel class of small molecules we developed that are structurally and functionally similar to naturally occurring molecules known to modulate inflammation. The lead product candidate from this program, VB-201, is a Phase 2-stage molecule that demonstrated activity in reducing vascular inflammation in a Phase 2 sub-study in psoriatic patients with cardiovascular risk.

In January 2021, we announced the dosing of the first patient in a randomized controlled Phase 2 study of VB-201 for the treatment of COVID-19. The study will assess the ability of VB-201 to prevent clinical deterioration and reduce morbidity and mortality in patients with severe COVID-19. Based on recent preclinical studies, we also believe that VB-201 and some second generation molecules such as VB-703 may have potential applicability for NASH and renal fibrosis.

In October 2017, we announced the opening of our new gene therapy pharmaceutical grade manufacturing plant in Modi'in, Israel. The facility was established to support the commercial supply of VB-111 for the first indication, if approved. The Modi'in facility is the first commercial-scale gene therapy manufacturing facility in Israel (20,000 sq. ft.). In July 2019, our facility was certified by a European Union (EU) Qualified Person (QP) as being in compliance with EU Good Manufacturing Practices (GMP). In November 2019 our facility was awarded by the Israeli Ministry of Health the Certificate of GMP Compliance of a Manufacturer.

In November 2017, we signed an exclusive license agreement with NanoCarrier Co., Ltd. (TSE Mothers:4571) for the development, commercialization, and supply of VB-111 in Japan. VBL retains rights to VB-111 in the rest of the world. Under terms of the agreement, VBL has granted NanoCarrier an exclusive license to develop and commercialize VB-111 in Japan for all indications. VBL will supply NanoCarrier with VB-111, and NanoCarrier will be responsible for all regulatory and other clinical activities necessary for commercialization in Japan. Under the agreement, VBL is entitled to receive greater than \$100 million in development and commercial milestone payments, in addition to tiered royalties on net sales in the high-teens.

In March 2019, we executed an exclusive option license agreement with an animal health company for the development of our proprietary anti-inflammatory molecule, VB-201, for veterinary use. We retain VB-201 rights for treatment of humans worldwide. Under the terms of the agreement, we have granted an exclusive option license to explore the potential of VB-201 for animal health indications. In consideration, we received an undisclosed up-front payment, and are entitled to receive additional development milestone payments. In April 2020, another milestone event under this agreement was reached, following which we received an undisclosed payment. If the option to license would be exercised, we will receive additional milestones and royalties on net sales.

In January 2021, we announced that we entered into an Ordinary Share Purchase Agreement with Aspire Capital Fund, LLC. Under the Agreement, Aspire has committed to purchase up to \$20 million of our ordinary shares at our discretion from time to time during a 30-month period at prices based on the market price at the time of each sale. We will retain full control as to the timing and amount of any sale of ordinary shares to Aspire, subject to certain limitations specified in the Purchase Agreement. There are no warrants or other derivative securities associated with the transaction. We have the right to terminate the Purchase Agreement at any time without any additional cost or penalty.

Our Strategy

Our goal is to become a leading biopharmaceutical company focused on discovering, developing and commercializing innovative therapeutics that leverage our proprietary technologies for oncology and immune/inflammatory indications. We intend to achieve this goal by pursuing the following strategies:

- **Pursue regulatory approval for our lead oncology drug candidate, VB-111**

We believe VB-111 has the potential for applications in various solid tumors. Currently, our focus is on development of VB-111 for platinum-resistant ovarian cancer. We launched the OVAL Phase 3 registration-enabling study for this indication in December 2017 and we expect to complete patient enrollment at the end of 2021 or in early 2022. OVAL is an event-driven study. We intend to advance VB-111 to additional cancer indications, either independently or through investigator-sponsored studies or strategic collaborations.

Based on the understanding that study regimen may be a key factor for VB-111 activity in rGBM, we believe the outcome of the GLOBE study will not necessarily have implications on the prospects for VB-111 in other regimens or tumor types. In March 2021, we announced that patient dosing has been initiated in a Phase 2 clinical trial investigating VB-111 for the treatment of rGBM. The Phase 2 study, sponsored by Dana-Farber Cancer Institute in collaboration with a group of top neuro-oncology US medical centers, will investigate neo-adjuvant and adjuvant treatment with VB-111 in rGBM patients undergoing a second surgery.

Similarly, in February 2020, we announced the launch of a Phase 2 clinical trial of VB-111 in combination with nivolumab (Opdivo[®]), an immune checkpoint inhibitor, in the treatment of metastatic colorectal cancer, under a Cooperative Research and Development Agreement (CRADA) between VBL and the National Cancer Institute (NCI). We also conducted Phase 2 clinical trial of VB-111 in thyroid cancer, with positive results.

- **Selectively enter into licensing and collaboration arrangements to supplement our internal development capabilities**


As we advance our pipeline of anti-cancer product candidates, we will evaluate opportunities to selectively form collaborative alliances for our non-oncology assets, such as the Lecinoxoids platform or the MOSPD2 mAbs for inflammation, to expand our capabilities and accelerate the development and commercialization of our oncology products. Accordingly, in March 2019, we announced a strategic exclusive option license agreement with one of the world-leading European animal health companies, for the development of VB-201 for veterinary use. We retain the VB-201 rights for treatment of humans, worldwide, as well as the global rights for other Lecinoxoids and VB-600 candidates. We engage in conversations with third parties to evaluate such potential collaborations on an ongoing basis.

- **Expand our manufacturing capacity to support clinical trials and possible commercialization of VB-111**

We previously manufactured clinical quantities of VB-111 at our facility in Or-Yehuda, Israel and through a third party in the United States. In October 2017, we announced the opening of our new gene therapy manufacturing plant in Modi'in, Israel. In July 2019, our facility was certified by a European Union (EU) Qualified Person (QP) as being in compliance with EU Good Manufacturing Practices (GMP). This plant can be the first commercial facility for production of VB-111 if it receives regulatory approval. On the longer term, we intend to have more than one manufacturing site for VB-111, if regulatory approved.

Our Product Candidates and Technology

The following table summarizes the status of pipeline:

Platform	Candidate	Program Area	Preclinical	Phase 1	Phase 2	Phase 3	Status	Partner/Collaborator	
Vascular Targeting System (VTS™) (gene therapy)	VB-111 (ofranergene obadenovec)	Ovarian Cancer (prOC)		Registration Enabling Study			OVAL	>50% enrolled	
		Colorectal Cancer		Nivolumab Combo				Recruiting	
		Recurrent Glioblastoma		Investigator Initiated				Recruiting	
		Thyroid Cancer (RAIR-DTC)		Phase 2 Completed				1° endpoint met	
Anti-MOSPD2 (mAbs)	VB-601	Anti-inflammatory					IND enabling studies		
	VB-611	Immuno-oncology							
Lecinoxoids (Oral anti-inflammatory small molecules)	VB-201	Severe COVID-19		Phase 2 exploratory trial				Recruiting	
		Atherosclerosis		Phase 2 Completed				1° endpoint met	
	VB-703	NASH, Renal Fibrosis							
		NASH							
		Renal Fibrosis							

Our VTS Platform

Overview

Our innovative, proprietary VTS platform technology enables systemic administration of gene therapy to either destroy or promote angiogenic blood vessels. VTS is both tissue- and condition-specific, allowing for targeted and limited gene expression in endothelial cells, the thin layer of cells that lines the interior surface of blood vessels undergoing angiogenesis.

Our VTS platform technology comprises three components, a viral vector, a promoter and a transgene:

1. Viral vector - a modified virus that is used as a delivery vehicle to distribute the promoter and the transgene throughout the body.
2. Promoter - our proprietary, genetically modified promoter, called PPE-1-3X, that specifically targets the endothelial cells of angiogenic blood vessels. When present in these cells, the promoter initiates the expression of the transgene.
3. Transgene - a genetic sequence designed to yield a specific biologic effect, the expression of which is directed by PPE-1-3X. The particular transgene will vary depending on the therapeutic objectives of the product candidate.

Once the gene therapy has reached the angiogenic blood vessels, the PPE-1-3X promoter activates expression of the transgene to produce a desired RNA or protein in the endothelial cells of those vessels. For oncology applications, the transgene selected is designed to destroy angiogenic blood vessels that feed solid tumors. For other potential applications, such as the treatment of ischemia, a different transgene can be selected that is designed to promote the development of angiogenic blood vessels instead of their destruction.

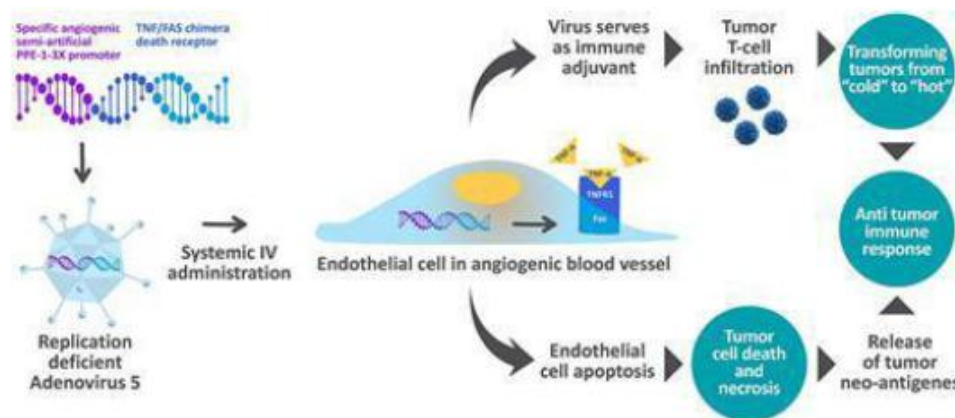
VB-111 (ofranergene obadenovec)

VB-111 is a unique biologic agent that uses a dual mechanism to target solid tumors. Its mechanism combines blockade of tumor vasculature with an anti-tumor immune response.

Based on a non-integrating, non-replicating, Adeno 5 vector, VB-111 utilizes our proprietary Vascular Targeting System (VTS) to target the tumor vasculature for cancer therapy. We designed VB-111 to address oncology indications, specifically solid tumors, by selectively targeting the blood vessels required for tumor growth and encouraging the programmed cell-death process, or apoptosis, of cells in those blood vessels. VB-111 is administered intravenously. PPE-1-3X is activated specifically in angiogenic endothelial cells and regulates a transgene consisting of a combination of two gene sequences known as Fas and TNFR1. When expressed, the transgene produces a unique pro-apoptotic protein, the Fas-TNFR1 chimera, that interacts with a native inflammatory molecule, Tumor Necrosis Factor, or TNF-alpha, and results in the destruction of newly formed or immature blood vessels. When activated by PPE-1-3X, specifically in angiogenic endothelial cells, this combination enables VB-111 to reduce tumor growth in a highly targeted manner.

In addition, VB-111 induces a specific anti-tumor immune response. The immunologic mechanism-of-action of viral-mediated anti-cancer therapies takes advantage of the natural interplay of viruses with the immune system and the ability of viruses to ‘kick-start’ immune reactions. In response to viral infection, cells within the tumor microenvironment express immune-stimulating cytokines attracting immune cells into the tumor. Furthermore, it is anticipated that the anti-angiogenic effect of VB-111 will trigger tumor starvation, destruction of tumor cells and subsequent release of cell debris and tumor neo-antigens that are ingested by antigen presenting cells, further stimulating the anti-tumor immune response. VB-111 specific expression in endothelial angiogenic cells focuses the immune reaction on tumor milieu and prevents systemic immune-mediated damage. In 2004, we published preclinical data, which suggested that there is an immune inflammatory response to the presence of the viral vector and the Fas-TNFR1 chimera. Support for a potential role of the immune system as part of VB-111’s mechanism of action came from an observation that patients who developed fever as a response to VB-111 administration, at least once along the treatment course, had a survival benefit over those who did not experience post-dosing fever. Moreover, an immunotherapeutic effect was also observed in biopsies taken from ovarian cancer patients. Immunohistochemistry staining showed regions of apoptotic cancer cells and infiltration of cytotoxic CD8 T-cells following treatment with VB-111.

VB-111’s mechanism of action is illustrated below:



Unlike anti-VEGF agents (such as Avastin[®]) or tyrosine-kinase inhibitors (TKIs), VB-111 does not aim to block a specific pro-angiogenic pathway; instead, it uses an angiogenesis-specific sensor (our PPE-1-3x proprietary promoter) to specifically induce cell death in angiogenic endothelial cells in the tumor milieu. This mechanism may retain activity regardless of baseline tumor mutations or the identity of the pro-angiogenic factors secreted by the tumor and shows activity even after failure of prior treatment with other anti-angiogenics. Moreover, VB-111 induces specific anti-tumor immune response, which is accompanied by recruitment of CD8 T-cells and apoptosis of tumor cells. We believe that this mode of action makes VB-111 less susceptible to resistance and, therefore, potentially applicable for a broader patient population than current therapies.

We have conducted preclinical studies in animal models of lung cancer, colon cancer, thyroid cancer, rGBM and melanoma. Based on those studies, and clinical results to date, we believe that VB-111 has anti-tumoral activity that may hold clinical promise and may be suitable for treatment of some solid tumors. We currently advance VB-111 in a randomized-controlled Phase 3 study in platinum-resistant ovarian cancer.

VB-111 Clinical Programs- Overview

We initially studied VB-111 in a Phase 1 “all comers” trial involving patients with multiple types of advanced metastatic cancer types, including thyroid cancer, neuroendocrine cancer, renal cell carcinoma and lung cancer. In that trial, VB-111 was well-tolerated and showed a dose-dependent extension in median overall survival across a range of tumor types. Based on these results, we decided to proceed with the development of VB-111 for rGBM, as well as to investigate VB-111 as a monotherapy for the treatment of thyroid cancer and, in combination with chemotherapy, for ovarian cancer. We have an open IND for VB-111 with the Office of Tissues and Advanced Therapies within FDA’s Center for Biologics Evaluation and Research.

VB-111 Clinical Program in Ovarian Cancer

Ovarian cancer is the leading cause of gynecologic cancer death in the United States affecting approximately 22,000 women annually. In patients with platinum-resistant disease, addition of the anti-angiogenic agent bevacizumab to chemotherapy has resulted in significantly improved PFS and response rate. However, the addition of bevacizumab did not result in a significant improvement of OS. Given the limited response to additional therapies, there is an unmet need to make significant improvements in the outcomes of patients with recurrent platinum-resistant ovarian cancer following first line therapy. Therefore, we conducted a Phase 1/2 clinical trial in ovarian cancer using VB-111 in combination with paclitaxel, a common chemotherapeutic agent.

This trial was designed as a Phase 1/2 dose escalation study. The primary objectives were to evaluate the safety and tolerability and identify dose limiting toxicity in combination of VB-111 and weekly paclitaxel; and explore the efficacy in an expanded cohort of the optimally tolerated dose of combination VB-111 and weekly paclitaxel, based on RECIST response, CA-125 response, progression free survival (PFS) and overall survival (OS) in patients with recurrent platinum-resistant ovarian cancer.

[Table of Contents](#)

Twenty one patients with recurrent platinum-resistant Müllerian/ovarian cancer were enrolled at Massachusetts General Hospital and Dana-Farber Cancer Institute, and received up to 7 doses of treatment. Patients were treated in two consecutive cohorts: Low Dose Treatment (n=4, 3x10¹² VPs + 40mg/80 mg paclitaxel) or a Therapeutic Dose (n=17, 1x10¹³ VPs + 80 mg paclitaxel). Papillary serous carcinoma was the most common histology (n=9, 42.9%); with other histologic subtypes including clear cell, adenocarcinoma, carcinosarcoma, and other (transitional/serous, mixed serous and clear-cell, and high grade serous with malignant mixed mullerian tumor components). The most common cancer stage at diagnosis was IIIC (n=12, 64.7%). Patients had been treated with a mean number of 2.6 prior therapies. Fifty-two percent received prior anti-angiogenic treatment, including Avastin, and 48% were considered platinum refractory having a platinum free interval of less than 3 months. Median age at enrollment was 65 (41-79).

Trial results showed a significant increase in overall survival at the therapeutic dose of VB-111 vs. the low dose level (498 vs. 172 days, p=0.03). Among the evaluable patients treated with the therapeutic dose, 58% (7/12) had a GCIG CA-125 response confirmed over four weeks. Mean duration of response was 10 months (range 1.5-24.9). Objective CA-125 response was associated with improved survival. Median OS was 808 vs. 351 days in patients with CA-125 decrease of 50% compared to those without 50% decrease in CA-125 (P=0.067). Post treatment fever occurred in 29% and was also associated with a signal for improved survival: median OS was 808 days in patients with fever compared to 479 days in patients without fever (p=0.27).

The 58% GCIG CA-125 response represents an approximate doubling in response rate, compared to historical data with ovarian cancer patients treated with a combination of Avastin[®] and chemotherapy in the AURELIA trial which reported CA-125 response in 11.6% of patients treated with chemotherapy and 31.8% CA-125 response in ovarian cancer patients treated with a combination of chemotherapy and Avastin[®].

An immunotherapeutic effect was also observed in biopsies taken from patients. H&E and immunohistochemistry staining showed regions of apoptotic cancer cells and infiltration of cytotoxic CD8 T-cells following treatment with VB-111. VB-111 was found to be safe and well tolerated. The most common VB-111 related AEs were transient mild-moderate fever/flu like symptoms, characteristic of infection with a viral vector. These events were generally grade 1-2 and responded to antipyretic treatment. No dose limiting toxicities were reported at any dose level.

In December 2016 we had an end-of-Phase 2 meeting with the FDA to discuss the clinical path of VB-111 in ovarian cancer. We reached agreement with the FDA on our clinical plan to proceed to a Phase 3 registration enabling study of VB-111 in platinum-resistant patients. We intend to advance VB-111 for this patient population, for which most current therapies fail to prolong patient survival, and in December 2017 announced the enrollment of the first patient in the OVAL registration enabling Phase 3 study of VB-111 in platinum-resistant ovarian cancer. The OVAL study is conducted in collaboration with the Gynecologic Oncology Group (GOG) Foundation, Inc., a leading organization for research excellence in the field of gynecologic malignancies.

The randomized, controlled, double-blind, Phase 3 OVAL international study in recurrent platinum-resistant ovarian cancer has been designed to enroll up to 400 adult patients at approximately 75 clinical sites in the United States, Europe, Israel and Japan. Patients are randomized 1:1 to VB-111 (1x10¹³ VPs once every 8 weeks) in combination with chemotherapy (80mg/m² paclitaxel once weekly), or to placebo with chemotherapy. The primary endpoint is overall survival. Additional endpoints include objective response rate (ORR), PFS, CA-125, RECIST 1.1 response and patient reported outcome measures.

In March 2020, we announced results of a pre-specified interim analysis in the OVAL study, which reviewed unblinded data and assessed CA-125 response, measured according to the GCIG criteria, in the first 60 enrolled subjects evaluable for CA-125 analysis. Based on the overall response rate in the first 60 patients across both arms of 53%, and assuming balanced randomization and an absolute advantage of 10% or higher to the VB-111 arm, the response rate in the treatment arm (VB-111 in addition to weekly paclitaxel) was calculated to be 58% or higher. In patients who had post-dosing fever, which is a marker for VB-111 treatment, the response rate was 69%. The futility rule determined for this analysis was that the response rate of VB-111 must be greater than the response rate of placebo by at least 10% in order to continue the study. This rule was successfully met. Based on the results of the interim analysis, the DSMC recommended continuing the trial as planned. Results of the interim analysis were published in an international peer reviewed journal (Arend *et al.*, Gynecol Oncol. 2021).

In August 2020, we announced that the DSMC completed its pre-planned review of unblinded Overall Survival (OS), response rate and safety data of the first 100 randomized patients with a follow-up of at least 3 months. The committee recommended that the study continue as planned. A subsequent DSMC pre-planned review of the OVAL study was announced in February 2021, with a dataset of 200 treated patients. The committee found no safety issues with the trial and recommended its continuation as planned.

The OVAL study is progressing according to plan. Periodic DSMC reviews in the OVAL study are planned twice a year. The next DSMC review is expected in the third quarter of 2021. We expect to complete patient enrollment in the OVAL study at the end of 2021 or in early 2022.

VB-111 Clinical Program in GBM

Glioblastoma is a brain cancer that affects approximately 12,000 to 13,000 newly diagnosed people each year in the United States. It is a devastating, rapidly progressing tumor, with a median time from diagnosis to the patient's death of 12 to 15 months. In recurrent glioblastoma, treatment consists of both symptomatic and palliative therapies. However, with currently available therapies, glioblastoma typically remains fatal within a very short period of time.

We conducted an open-label Phase 2 trial in rGBM, which was originally initiated as an adaptive Phase 1/2 trial. The trial was intended to evaluate the safety and efficacy of VB-111, both by itself and in combination with bevacizumab, an anti-angiogenesis agent approved by the FDA for use in rGBM. In this trial, patients were initially dosed with VB-111 alone. After disease progression on VB-111 alone, they receive either bevacizumab alone as standard of care, or, in a second cohort, a combination of VB-111 and bevacizumab. Disease progression was defined as a worsening of the patient's cancer with an increase of at least 25% in the overall mass of measurable tumors, the appearance of new tumors, the worsening of non-measurable tumors since beginning of treatment, a need for an increased dose of corticosteroids or clinical deterioration.

Our Phase 2 trial results include 46 patients with rGBM treated with VB-111; upon disease progression, 23 patients were treated with VB-111 in combination with Avastin[®], and 22 received Avastin[®] alone. One patient, who received VB-111 monotherapy and achieved a complete response, is stable for more than 6 years as of January 2020, and was included in the continuous exposure cohort. The median number of bi-monthly VB-111 doses was four for the cohort, which was treated with VB-111 through progression, versus one in the limited exposure cohort (average of 4.7 vs. 2.2, respectively). Continuous exposure to VB-111 demonstrated significant improvement in overall survival, with median overall survival of 59.1 weeks (414 days), compared to 31.9 weeks (223 days) in patients on limited VB-111 exposure (p=0.043), meeting the primary endpoint of the trial. Two complete responses and five partial responses were seen in the VB-111 continuous exposure cohort (n=24), compared to only two partial responses in VB-111 limited exposure cohort (n=22). VB-111 was found to be well tolerated.

The trial data also showed that VB-111 may induce an immuno-therapeutic effect. Of the 46 patients who received VB-111, 25 patients experienced a fever post-dosing of VB-111 at least once, while 21 patients did not. Patients with fevers demonstrated increased overall survival of 16 months, compared to patients without fevers, who had a median overall survival of 8.5 months ($p=0.03$). Additional biomarkers analyses presented at the SNO conference in November 2017 have demonstrated that in addition to fever, VB-111 is also associated with immune-mediated responses, including secretion of immune-stimulatory cytokines that correlate with OS, further supporting a role of the immune system as part of VB-111's dual mechanism of action.

In June 2016 at the ASCO conference, we presented clinical data that demonstrate a significant overall survival benefit in rGBM patients receiving VB-111 compared with historical Avastin[®] meta-analysis data. In the Phase 2 VB-111 trial, the median overall survival of patients who received continuous exposure of VB-111 in combination with Avastin was 59.1 weeks. This is compared to 32.1 weeks in the pooled data from the 8 studies in the meta-analysis ($p=0.0295$; Hazard Ratio 0.62, 95% CI: 0.40-0.96). Median survival ranged from 26.0 weeks to 45.7 weeks in the meta-analysis. Overall survival at 12 months for patients on continuous exposure of VB-111 was 57%, compared with 24% overall survival (range 16%-38%) for the pooled Avastin[®] treated rGBM data ($p=0.03$).

In 62 patients with rGBM, the most frequent toxicity was self-limited fever, starting several hours post therapy and usually resolving within 24 hours and controlled with anti-pyretics. There were 22 adverse events classified as grade 3 or higher, of which 7 were considered possibly related to VB-111 including asthenia, pyrexia, brain edema, depressed consciousness, pulmonary embolism, or PE (in a patient with PE prior to enrollment in the trial) and hypertension. Safety results were reviewed five times by the trial Data and Safety Monitoring Board, as well as by the FDA, without safety concerns. Based on interim Phase 2 data of VB-111 in rGBM, the FDA has allowed VBL to launch a Phase 3 study of VB-111 in rGBM patients prior to the completion of the Phase 2 trial.

Our Phase 3 GLOBE study in rGBM compared upfront concomitant administration of VB-111, without priming, and bevacizumab to bevacizumab monotherapy. The study, which enrolled a total of 256 patients in the US, Canada and Israel was conducted under a special protocol assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA, with full endorsement by the Canadian Brain Tumor Consortium (CBTC).

Three safety reviews were conducted during the GLOBE trial, by the independent DSMC. In December 2016, we announced that the DSMC reviewed the GLOBE safety data collected through a cutoff date in September 2016, and did not find any adverse events that would be cause for concern. As a result, the DSMC recommended that the study continue as planned. In April 2017, we announced that the committee reviewed the GLOBE safety data collected through a cutoff date in March 2017 and unanimously recommended that the study continue as planned. The third and final DSMC review took place in September 2017. The committee reviewed the GLOBE safety data, including mortality data, collected through a cutoff date in August 2017, and stated that they did not identify any safety concerns. The DSMC confirmed that no additional follow up will be necessary. Accordingly, the DSMC unanimously recommended that the study continue as planned, to completion.

On March 8, 2018, we announced top-line data from the GLOBE study. In this modified regimen, the treatment did not improve overall survival (OS) and PFS outcomes in rGBM. No new safety concerns associated with VB-111 have been identified in the GLOBE study. Thorough analyses of the baseline risk factors of the Phase 2 and the Phase 3 treatment groups did not reveal any differences. Therefore, patient selection or different patient populations could not explain the difference between the results of the two studies.

Study results (Cloughesy *et al.* Neuro Oncol. 2019) attribute the contradictory outcomes between the Phase 2 and Phase 3 trials as being related to the lack of VB-111 monotherapy priming in the GLOBE study, providing clinical, mechanistic and radiographic support for this hypothesis. Notably, GLOBE data show improved outcomes associated with a post VB-111 fever reaction, similar to outcomes from previous VB-111 studies, providing support that fever is a potential biomarker for better survival with VB-111, secondary to the drug's immunologic mechanism of action.

Based on the understanding that study regimen may be a key factor for VB-111 activity in rGBM, we believe the outcome of the GLOBE study will not necessarily have implications on the prospects for VB-111 in other regimens or tumor types. In March 2021, we announced that patient dosing has been initiated in a Phase 2 clinical trial investigating VB-111 for the treatment of rGBM. The Phase 2 study, sponsored by Dana-Farber Cancer Institute in collaboration with a group of top neuro-oncology US medical centers, will investigate neo-adjuvant and adjuvant treatment with VB-111 in rGBM patients undergoing a second surgery.

VB-111 Program in Thyroid Cancer

We conducted an exploratory Phase 2 clinical trial to evaluate safety and efficacy of VB-111 in advanced thyroid cancer. According to the National Cancer Institute (seer.cancer.gov), in 2017, there were an estimated 859,838 people living with thyroid cancer in the United States. The estimated number of new US cases of thyroid cancer in 2020 was 52,890. Most cases can be treated by surgery and radioactive iodine. If radioactive iodine is ineffective, other treatments are prescribed, such as tyrosine kinase inhibitors and systemic chemotherapy. However, if such treatments are unsuccessful, the therapeutic options for patients are currently very limited. This subset of patients has an unmet need for novel therapeutic options. The estimated number of US deaths of thyroid cancer in 2020 was 2,180.

Our open-label dose-escalating study enrolled patients with advanced, recently-progressive, differentiated thyroid cancer that was unresponsive to radioactive iodine, in two cohorts. Most patients had tumors that had not responded to multiple therapies prior to enrollment, including radiation and kinase inhibitors. In the first cohort, thirteen patients received a single intravenous infusion of VB-111 at a sub-therapeutic dose of 3×10^{12} viral particles (VPs).

The second cohort included seventeen patients, who received VB-111 at a therapeutic dose of 10^{13} VPs every two months until disease progression. One patient proceeded from a single low dose to receive later multiple high doses at progression and was included in both groups (for PFS only).

On February 21, 2017, we announced full data from this trial. The primary endpoint of the trial, defined as 6-month progression-free-survival (PFS-6) of 25%, was met with a dose response. Forty-seven percent (47%; 8/17) of patients in the therapeutic-dose cohort reached PFS-6, versus 25% (4/12) in the sub-therapeutic cohort, both groups meeting the primary endpoint. Reduction in tumor measurement after the first dose was seen in 44% (7/16) of patients in the therapeutic-dose cohort, compared to 9% (1/11) in the sub-therapeutic-dose cohort. An overall survival benefit was seen with a tail of more than 40% at 3.7 years for the therapeutic-dose cohort (mOS 684 days). This is similar to historical data for pazopanib (Votrient[®]), a tyrosine kinase inhibitor; however, most patients in the VB-111 study had tumors that previously had progressed on pazopanib or other kinase inhibitors. VB-111 was observed to be well-tolerated in this study, with no signs of clinically significant safety issues.

We see these positive data as additional proof-of-concept for VB-111 in another advanced solid tumor, particularly important for investigating the therapeutic potential of VB-111 even as monotherapy. Our primary focus continues to be advancement of VB-111 towards commercialization, if approved, in ovarian cancer. Further clinical development of VB-111 for thyroid cancer may also be pursued, potentially with a strategic partner, or via an investigator-sponsored study.

VB-111 Program in Colorectal Cancer

Based on support from preclinical data, which we presented at the American Society of Gene & Cell Therapy (ASGCT) conference in May 2017, and histological data in ovarian cancer showing the ability of VB-111 to recruit T-cells into ‘cold’ tumors, we believe that treatment with VB-111 may be further enhanced by addition of immune checkpoint inhibitors.

In February 2020, we announced the launch of a Phase 2 clinical trial of VB-111 in combination with nivolumab (Opdivo[®]), an immune checkpoint inhibitor, in the treatment of metastatic colorectal cancer under a Cooperative Research and Development Agreement (CRADA) between VBL and the National Cancer Institute (NCI). NCI serves as the IND sponsor for this study. The open label exploratory Phase 2 study will investigate if priming with VB-111 can drive immune cells into the tumor and turn the colorectal tumors from being immunologically “cold” to “hot.” Enrollment in this clinical trial started in September 2020. A preliminary readout in this study is expected in the first half of 2021.

Additional VTS Pipeline candidates

Our VTS platform technology enables systemic administration of gene therapy to either destroy or promote angiogenic blood vessels. Beyond VB-111, we have generated additional preclinical product candidates which utilize the same vector and promoter as in VB-111, yet comprise alternative functional transgenes. VB-511 is an anti-angiogenic candidate, while VB-211 and VB-411 are pro-angiogenic candidates that may be employed for ischemic conditions like peripheral vascular disease.

Expanding our Pipeline - The VB-600 series of monoclonal antibodies targeting MOSPD2 for Inflammation and Oncology

We are conducting two parallel drug development programs that are exploring the potential of MOSPD2, a protein which we identified as a key regulator of cell motility, as a therapeutic target for inflammatory diseases and cancer.

MOSPD2 is a membrane protein whose function was unknown. We discovered new biological findings, which seem to position MOSPD2 as a critical pathway controlling monocyte migration and as a key regulator of disease pathogenesis in different inflammatory autoimmune settings. Our data show that inhibition of MOSPD2 by either knockdown, silencing or proprietary antibodies, results in a significant reduction in the ability of monocytes to migrate, regardless of the inflammatory signals employed to attract them.

Since many of the receptors involved in regulation of immune cell migration are also utilized by cancer cells in the process of dissemination through the body and formation of metastases, we asked whether MOSPD2 plays a role in this setting as well. We found that MOSPD2 was detected in the majority of cancerous organs, including colon, esophagus, liver and breast. In a manuscript published in the International Journal of Cancer as well as in scientific conferences, we showed that MOSPD2 is required for the migration and invasion of breast cancer cells in vitro, and that it promotes breast cancer cell metastasis in vivo. Given the specificity of MOSPD2 expression and its highly elevated expression in tumors, we believe MOSPD2 can serve as a novel mechanism for targeting of tumor cells.

Classical mAbs for Inflammatory Indications

Our data show that MOSPD2 which is predominantly expressed on the surface of human monocytes, is essential for their migration. By inhibiting this protein, we seek to block this migration of monocytes to sites of inflammation, and accordingly to reduce inflammation and tissue damage.

At the ECTRIMS 2018 meeting, we presented the critical role of MOSPD2 in the development of multiple sclerosis (MS) and its potential as a novel target for treatment of inflammation in the Central Nervous System (CNS) and other organs. One of the key cell types that causes inflammation in MS is the monocyte. In MS, monocytes that circulate in the peripheral blood infiltrate into the CNS and play a key role in the inflammatory process, particularly through damaging the myelin coating which protects the nerve fibers, therefore leading to acute neurological symptoms. Using MOSPD2 knockout mice, our data show that MOSPD2 was critical for the development of the disease in the experimental autoimmune encephalomyelitis (EAE) model for MS, as knockout mice essentially do not develop the disease. Furthermore, we developed proprietary monoclonal antibodies against MOSPD2 that successfully prevented development of EAE, and also showed activity in treatment of the animals after the neurological symptoms had already appeared.

In September 2020, at the MS Virtual 2020 Meeting, we presented human proof-of-concept data that showed that our anti-MOSPD2 mAbs significantly inhibited migration of monocytes isolated from all MS patients included in the study (n=33) by up to 97% (p<0.001), regardless of disease severity, gender or active treatment. The activity was seen not only in the monocytes from relapsing-remitting patients, but also those from primary progressive and secondary progressive patients with high Expanded Disability Status Scale (EDSS) scores of 5.5-6.5. These clinical data are backed up by strong preclinical studies (Yacov *et al.*, Clin Exp Immunol. 2020). We believe that our antibodies offer a novel mechanism for potential treatment of MS, through blocking the accumulation of monocytes/macrophages in the central nervous system, which is differentiated from the existing available treatments, which mostly target T and B cells.

In May 2020, we presented data at the Digestive Disease Week® (DDW) 2020 virtual meeting, demonstrating that treatment with anti-MOSPD2 antibody decreased inflammation and fibrosis in a NASH model and reduced the disease activity in a colitis model. Knockout of MOSPD2 also led to reduction in liver fibrosis in a high-fat-high-carbohydrate model for NASH.

In June 2020, we presented data at the European League Against Rheumatism (EULAR) 2020 Congress, demonstrating the potential of anti-MOSPD2 mAbs for treatment of RA with differentiation from anti-TNF treatment. Data presented at Keystone symposia in February 2019 showed that mice in which the MOSPD2 gene was knocked out had minimal or no disease in the collagen antibody-induced arthritis model for RA.

We believe that antibodies targeting MOSPD2 have potential for treatment of various inflammatory indications, and are advancing our lead preclinical candidate VB-601 through IND-enabling studies. In September 2020, we announced the successful completion of a Type B pre-IND meeting with the FDA regarding our development plan for VB-601. Toxicology studies for VB-601 are currently underway. Submission of an IND for the clinical development of VB-601 is expected to occur in the first half of 2022.

Anti-MOSPD2 mAbs for Oncology Indications

We found that MOSPD2 was detected in the majority of cancerous organs, including colon, esophagus, liver and breast, where MOSPD2 seems to play a key role in cancer cell metastasis (Salem *et al.*, Int J. Cancer 2019). Our preliminary data indicate that knock-out of MOSPD2 in tumor cells may reduce metastasis by 95% in some preclinical settings.

Based on these findings, our approach is to utilize MOSPD2 as a target for attacking tumor cells. We presented preclinical proof-of-concept for this approach in April 2018 at the AACR conference using a BiTE antibody, and in June 2020 using bi-specific full-IgG antibody candidates.

In October 2020, we announced that the European Patent Office (EPO) granted Patents #3328408 and #3328401, which cover VBL's proprietary investigational anti-MOSPD2 monoclonal antibodies to treat inflammatory conditions and oncology conditions, respectively. The patents are expected to provide protection for VBL's MOSPD2 antibodies for inflammation and cancer, until at least July 2036.

Our Lecinoxoid Platform Technology

Our proprietary Lecinoxoid platform technology comprises a family of orally administered small molecules designed to modulate the body's inflammatory response. Lecinoxoids are compounds that are structurally and functionally similar to naturally occurring molecules, known as oxidized phospholipids, which possess immune modulating anti-inflammatory properties, modified to enhance stability and activity. We believe that Lecinoxoids hold significant promise in their ability to treat a range of chronic immune-based inflammatory diseases.

The inflammatory response is a complex physiologic process balancing both pro- and anti-inflammatory components that interact intimately with the body's immune system. Oxidized phospholipids are instrumental in the interplay of these components that maintain equilibrium. When the inflammatory response is not adequately balanced, excess inflammation results and may cause both acute and chronic disease states. We believe that by identifying naturally occurring anti-inflammatory compounds and modifying them to enhance stability and activity we may achieve more physiologically balanced responses than other available anti-inflammatory therapies.

VB-201

Our lead Lecinoxoid-based product candidate, VB-201, was designed as an oral agent for the control of chronic inflammatory disorders. VB-201 is a Phase 2-stage immune-modulator that demonstrated activity in reducing vascular inflammation in a Phase 2 sub-study in psoriatic patients with cardiovascular risk. It was also clinically studied for psoriasis and ulcerative colitis, however, our data did not support further development for these indications. VB-201 has demonstrated tolerability in over 600 patients across eight clinical trials. We believe that VB-201 has potential in other disorders in which TLR-2 and TLR-4 or monocytes play a role, such as atherosclerosis, NASH/Liver fibrosis and renal fibrosis.

As monocytes/macrophages play a key role in the cytokine storm seen with COVID-19, targeting their accumulation in the lungs represents an encouraging strategy for curbing hyper-inflammation and tissue damage. In January 2021, we announced the dosing of the first patient in a randomized controlled Phase 2 study of VB-201 for the treatment of COVID-19. The study will assess the ability of VB-201 to prevent clinical deterioration and reduce morbidity and mortality in patients with severe COVID-19. This exploratory open-label study is designed to enroll 30 patients, randomized in equal ratio to VB-201 plus standard of care versus standard of care. The study is being conducted in Israel and is currently recruiting patients. For additional information see ClinicalTrials.gov Identifier: NCT04733833.

In March 2019, we executed an exclusive option license agreement with an animal health company for the development of our proprietary anti-inflammatory molecule, VB-201, for veterinary use. We retain VB-201 rights for treatment of humans worldwide. Under the terms of the agreement, we have granted an exclusive option license to explore the potential of VB-201 for animal health indications. In consideration, we received an undisclosed up-front payment, and are entitled to receive additional development milestone payments. In April 2020, another milestone event under this agreement was reached, following which we received an undisclosed payment. If the option to license would be exercised, we will receive additional milestones and royalties on net sales.

Beyond VB-201, we have developed second and third generations of Lecinoxoid product candidates. Our results highlight the potential of some of these molecules, such as VB-703, a third generation candidate whose IP life-cycle can extend to the mid-2030s.

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.

Patents

As of February 22, 2021, we had 203 granted patents and 30 applications pending worldwide for our oncology program and VTS platform technology and 166 granted patents and 10 patent applications pending worldwide for our anti-inflammatory program and Lecinoxoid family of compounds. For our MOSPD2 programs in oncology and immune/inflammation, we had 13 granted patents and 27 applications pending worldwide. Our lead VTS asset, VB-111, is covered by US granted patent extending to 2033 before any extensions. Our lead Lecinoxoid, VB-201, is protected by US granted composition-of-matter patent extending to 2027 before any extensions. In addition, we have granted patents and pending patent applications covering use of VB-201, VB-703 and additional Lecinoxoid for NASH and fibrosis indications that extend to the 2030s. We also have a pending patent application covering use of VB-201, VB-703 and additional Lecinoxoid for coronavirus indications that may extend, if granted, to the 2040s.

Trademarks

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

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. For a more comprehensive summary of the risks related to our intellectual property, see “Risk Factors.”

Sales and Marketing

We have not yet established sales, marketing or product distribution operations because our lead candidates are still in early clinical development.

Manufacturing

We generally perform process development for our drug substance candidates and manufacture quantities of our drug candidates necessary to conduct preclinical studies and clinical trials of our drug candidates. We rely on third-party manufacturers to produce bulk drug substance required for our clinical trials and expect to continue to rely on third parties to manufacture clinical trial drug supplies for the foreseeable future. We also contract with additional third parties for the formulating, labeling, packaging, storage and distribution of the final drug products.

VB-111

Until late 2017, we manufactured the active pharmaceutical ingredient and the formulated drug product of VB-111 for the clinical development at our small-scale cGMP-compliant production facility in Or-Yehuda, Israel and pursuant to an arrangement with a third party in the United States.

In October 2017, we announced the opening of our new gene therapy manufacturing plant in Modi'in, Israel. This plant will be the commercial facility for production of the Company's lead product candidate, VB-111, if approved. The site design enables modular expansion of the manufacturing capacity, to supply growing demand following commercialization. The Modi'in facility shall also enable us to comply with the restrictions of the Research Law and our undertaking to the OCS that an essential portion of our VB-111 production, and in any event not less than the majority of VB-111 production, will remain in Israel. In July 2019, our facility was certified by a European Union (EU) Qualified Person (QP) as being in compliance with EU Good Manufacturing Practices (GMP). In November 2019 our facility was awarded by the Israeli Ministry of Health the Certificate of GMP Compliance of a Manufacturer.

Employees

As of March 1, 2021, we employed 38 employees, including 30 in research and development, and 8 in general and administrative positions, and of which 12 employees have either MDs or PhDs. All of our employees are located in Israel. We believe our employee relations are good.

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.

None of our employees currently work under any collective bargaining agreements.

Property

Our corporate headquarters and research facilities are currently located in Modi'in, Israel, where we lease an aggregate of approximately 21,500 square feet of office and laboratory space, pursuant to a lease agreement that expires in May 2024. This facility additionally houses our clinical development, clinical operations, regulatory and management functions, as well as our local biological drugs manufacturing facility.

Organizational Structure

We do not have any subsidiaries.

Legal Proceedings

We are not a party to any legal proceedings.

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

The following discussion of our financial condition and results of operations should be read in conjunction with “Item 3. Key Information-Selected Financial Data” and 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. 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 3. Key Information-D. Risk Factors” and elsewhere in this Annual Report.

The audited financial statements for the years ended December 31, 2020, 2019 and 2018 and as of December 31, 2020 and 2019 in this Annual Report have been prepared in accordance with U.S. GAAP.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class treatments for areas of unmet need in cancer and immune/inflammatory indications. We have developed three platform technologies: a gene-therapy based technology for targeting newly formed blood vessels with focus on cancer, an antibody-based technology targeting MOSPD2 for immuno-oncology and anti-inflammatory applications, and the Lecinoxoids, a family of small-molecules for chronic immune-related indications.

Our main program in oncology is based on our proprietary Vascular Targeting System, or VTS, platform technology, which we believe will allow us to develop product candidates for multiple oncology indications. The VTS technology utilizes genetically targeted therapy to destroy newly formed, or angiogenic, blood vessels. By utilizing a viral vector as a delivery mechanism, the VTS platform can also lead to induction or enhancement of a localized anti-tumor immune response, thereby turning immunologically ‘cold’ tumors ‘hot’.

[Table of Contents](#)

Our lead product candidate, VB-111, is a gene-based biologic that we are developing for solid tumor indications, and which we have advanced to programs for ovarian cancer, recurrent glioblastoma, or rGBM, an aggressive form of brain cancer, and thyroid cancer. We have obtained fast track designation for VB-111 in the United States for prolongation of survival in patients with glioblastoma that has recurred following treatment with standard chemotherapy and radiation. We have also received orphan drug designation for GBM in both the United States and Europe. VB-111 has also received an orphan designation for the treatment of ovarian cancer by the European Commission.

OVAL is our international Phase 3 randomized pivotal registration enabling clinical trial that compares a combination of VB-111 and paclitaxel to placebo plus paclitaxel, in patients with platinum-resistant ovarian cancer. The study is planned to enroll 400 patients. In March 2020, we announced the outcome of the planned interim analysis in the OVAL study. The OVAL independent Data Safety Monitoring Committee (DSMC) reviewed unblinded data and assessed CA-125 response, measured according to the GCIG criteria, in the first 60 enrolled subjects evaluable for CA-125 analysis. The DSMC confirmed that the study met the interim pre-specified efficacy criterion, of an absolute percentage advantage of 10% or higher CA-125 response rate for the VB-111 treatment arm, and recommended the study continue. The overall response rate in the first 60 randomized evaluable patients was 53%. Assuming a balanced randomization, the response rate in the treatment arm (VB-111 in addition to weekly paclitaxel) was 58% or higher. In patients who had post-dosing fever, which is a marker for VB-111 treatment, the response rate was 69%. Results of the interim analysis were published in a peer-review manuscript (Arend *et al.*, *Gynecol Oncol.* 2021).

The following analysis of the OVAL study was conducted in August 2020. The DSMC reviewed unblinded overall survival (OS) data of the first 100 enrolled subjects with a follow-up of at least 3 months. The committee also looked at response rate and safety information. The DSMC recommended that the study continue as planned. The primary endpoint of the OVAL Phase 3 study is OS.

In February 2021, we announced the results of a subsequent DSMC pre-planned review of the OVAL study. The committee, which reviewed unblinded data of 200 treated patients, found no safety issues with the trial and recommended its continuation as planned. The next DSMC review in the OVAL study is expected in the third quarter of 2021. Our OVAL study is being conducted in collaboration with the GOG Foundation, Inc., a leading organization for research excellence in the field of gynecologic malignancies.

Final results from our Phase 1/2 clinical trial of VB-111 for recurrent platinum-resistant ovarian cancer were reported in June 2019 and published online in April 2020 (Arend *et al.*, *Gynecol Oncol.* 2020). Data demonstrated a median OS of 498 days in the VB-111 therapeutic-dose arm, versus 172.5 days in the low-dose arm ($p=0.03$). 58% of evaluable patients treated with the therapeutic dose of VB-111 had a GCIG CA-125 response. VB-111 activity signals were seen despite unfavorable prognostic characteristics (48% platinum refractory disease and 52% previous treatment with anti-angiogenics). There was a trend for favorable survival in patients who had CA-125 decrease $>50\%$ in the VB-111 therapeutic-dose arm (808 vs. 351 days; $p=0.067$) implicating CA-125 as a potentially valuable biomarker for response to VB-111. Post treatment fever was also associated with a signal for improved survival (808 vs. 479 days; $p=0.27$).

In a Phase 2 study for rGBM, patients who were primed with VB-111 monotherapy that was continued after progression with the addition of bevacizumab (Avastin[®]) showed significant survival (414 vs 223 days; HR 0.48; $p=0.043$) and progression free survival (PFS) advantage (90 vs 60 days; HR 0.36; $p=0.032$) compared to a cohort of patients that had limited exposure to VB-111 (Brenner *et al.*, *Neuro Oncol.* 2019). Radiographic responders to VB-111 exhibited specific imaging characteristics related to its mechanism of action. Survival advantage was also seen in comparison to historic controls, with the percentage of patients living more than one year doubling from 24% to 57%.

Our Phase 3 GLOBE study in rGBM compared upfront concomitant administration of VB-111, without priming, and bevacizumab to bevacizumab monotherapy. The study, which enrolled a total of 256 patients in the US, Canada and Israel was conducted under a special protocol assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA, with full endorsement by the Canadian Brain Tumor Consortium (CBTC). In this modified regimen, the treatment did not improve overall survival (OS) and PFS outcomes in rGBM. Study results (Cloughesy *et al.* *Neuro Oncol.* 2019) attribute the contradictory outcomes between the Phase 2 and Phase 3 trials as being related to the lack of VB-111 monotherapy priming in the GLOBE study, providing clinical, mechanistic and radiographic support for this hypothesis. Notably, GLOBE data show improved outcomes associated with a post VB-111 fever reaction, similar to outcomes from previous VB-111 studies, providing support that fever is a potential biomarker for better survival with VB-111, secondary to the drug's immunologic mechanism of action. No new safety concerns associated with VB-111 have been identified in the study. We do not think that results of the GLOBE study will necessarily have implications on the prospects for VB-111 in other regimens or tumor types.

On March 1, 2021, we announced that patient dosing has been initiated in a Phase 2 clinical trial investigating VB-111 for the treatment of rGBM. The new Phase 2 study, sponsored by Dana-Farber Cancer Institute in collaboration with a group of top neuro-oncology US medical centers, will investigate neo-adjuvant and adjuvant treatment with VB-111 in rGBM patients undergoing a second surgery.

In February 2020, we announced the launch of a phase 2 clinical trial of VB-111 in combination with nivolumab (Opdivo[®]), an immune checkpoint inhibitor, in the treatment of metastatic colorectal cancer. Under a Cooperative Research and Development Agreement (CRADA) between VBL and the National Cancer Institute (NCI), NCI will serve as the IND sponsor for this study. IND application for the study has been approved by the FDA. This new study will investigate if priming with VB-111 can drive immune cells into the tumor and turn the colorectal tumor from immunologically 'cold' to 'hot'. The addition of nivolumab to VB-111 may further boost the anti-tumor immune response.

VB-111 is also being studied in combination with nivolumab, an anti-PD1 immune checkpoint inhibitor, in the treatment of metastatic colorectal cancer. The study is being sponsored by the U.S. National Cancer Institute under a Cooperative Research and Development Agreement, or CRADA. The open label exploratory Phase 2 study will investigate if priming with VB-111 can drive immune cells into the tumor and turn the colorectal tumors from being immunologically "cold" to "hot." Enrollment in this clinical trial started in September 2020. A preliminary readout in this study is expected in the first half of 2021.

In February 2017, we reported full data from our exploratory Phase 2 study of VB-111 in recurrent, iodine-resistant differentiated thyroid cancer. The primary endpoint of the trial, defined as 6-month progression-free-survival (PFS-6) of 25%, was met with a dose response. Forty-seven percent of patients in the therapeutic-dose cohort reached PFS-6, versus 25% in the sub-therapeutic cohort, both groups meeting the primary endpoint. An overall survival benefit was seen, with a tail of more than 40% at 3.7 years for the therapeutic-dose cohort, similar to historical data for pazopanib (Votrient[®]), a tyrosine kinase inhibitor; however, most patients in the VB-111 study had tumors that previously had progressed on pazopanib or other kinase inhibitors.

Over 300 patients were exposed to VB-111 in completed clinical trials and it has been observed to be well-tolerated. In December 2015, we have been granted a US composition of matter patents that provides intellectual property protection for VB-111 in the US until October 2033 before any patent term

[Table of Contents](#)

We are also conducting two parallel drug development programs that are exploring the potential of MOSPD2, a protein that we identified as a key regulator of cell motility, as a therapeutic target for inflammatory diseases and cancer.

For inflammatory applications, we are developing classical antibodies that are designed to bind and block MOSPD2 on immune cells. Our data show that MOSPD2, which is predominantly expressed on the surface of human monocytes, is essential for their migration. By inhibiting this protein, we seek to block this migration of monocytes to sites of inflammation, and accordingly to reduce inflammation and tissue damage. We believe that antibodies targeting MOSPD2 have potential for treatment of various inflammatory indications, and are advancing our lead preclinical candidate VB-601 through IND-enabling studies. In September 2020, we announced the successful completion of a Type B pre-IND meeting with the FDA regarding our development plan for VB-601. Toxicology studies for VB-601 are currently underway. Submission of an IND for the clinical development of VB-601 is expected to occur in the first half of 2022.

For oncology applications, we are developing antibodies aimed to kill tumor cells, based on MOSPD2 as a target whose expression is induced in multiple tumors. We found that MOSPD2 was detected in the majority of cancerous organs, including colon, esophagus, liver and breast, where MOSPD2 seems to play a key role in cancer cell metastasis (Salem *et al.*, *Int J. Cancer* 2019). Given the specificity of MOSPD2 expression and its highly elevated expression in tumors, we believe MOSPD2 can serve as a novel target for immuno-oncology mediated therapy for cancer.

In October 2020, we announced that the European Patent Office (EPO) has granted Patents #3328408 and #3328401, which cover VBL's proprietary investigational anti-MOSPD2 monoclonal antibodies to treat inflammatory conditions and oncology conditions, respectively. The patents are expected to provide protection for VBL's MOSPD2 antibodies for inflammation and cancer, until at least July 2036.

We also have been conducting a program targeting anti-inflammatory diseases, based on the use of our Lecinoxoid platform technology. Lecinoxoids are a novel class of small molecules we developed that are structurally and functionally similar to naturally occurring molecules known to modulate inflammation. The lead product candidate from this program, VB-201, is a Phase 2-stage molecule that demonstrated efficacy in reducing vascular inflammation in a Phase 2 sub-study in psoriatic patients with cardiovascular risk. Due to business limitations associated with the heavy burden of developing medications for cardiovascular diseases, we chose to test it in psoriasis and ulcerative colitis; however, as we reported in February 2015, VB-201 failed to meet the primary endpoint in Phase 2 clinical trials for psoriasis and for ulcerative colitis.

In January 2021, we announced the dosing of the first patient in a randomized controlled Phase 2 study of VB-201 for the treatment of COVID-19. The study will assess the ability of VB-201 to prevent clinical deterioration and reduce morbidity and mortality in patients with severe COVID-19. Based on recent preclinical studies, we also believe that VB-201 and some second generation molecules such as VB-703 may have potential applicability for NASH and renal fibrosis.

In October 2017, we announced the opening of our new gene therapy pharmaceutical grade manufacturing plant in Modi'in, Israel. The facility was established to support the commercial supply of VB-111 for the first indication, if approved. The Modi'in facility is the first commercial-scale gene therapy manufacturing facility in Israel (20,000 sq. ft.). In July 2019, our facility was certified by a European Union (EU) Qualified Person (QP) as being in compliance with EU Good Manufacturing Practices (GMP). In November 2019 our facility was awarded by the Israeli Ministry of Health the Certificate of GMP Compliance of a Manufacturer.

In November 2017, we signed an exclusive license agreement with NanoCarrier Co., Ltd. (TSE Mothers:4571) for the development, commercialization, and supply of VB-111 in Japan. VBL retains rights to VB-111 in the rest of the world. Under terms of the agreement, VBL has granted NanoCarrier an exclusive license to develop and commercialize VB-111 in Japan for all indications. VBL will supply NanoCarrier with VB-111, and NanoCarrier will be responsible for all regulatory and other clinical activities necessary for commercialization in Japan. Under the agreement, VBL is entitled to receive greater than \$100 million in development and commercial milestone payments, in addition to tiered royalties on net sales in the high-teens.

In March 2019, we executed an exclusive option license agreement with an animal health company for the development of our proprietary anti-inflammatory molecule, VB-201, for veterinary use. We retain VB-201 rights for treatment of humans worldwide. Under the terms of the agreement, we have granted an exclusive option license to explore the potential of VB-201 for animal health indications. In consideration, we received an undisclosed up-front payment, and are entitled to receive additional development milestone payments. In April 2020, another milestone event under this agreement was reached, following which we received an undisclosed payment. If the option to license would be exercised, we will receive additional milestones and royalties on net sales.

In January 2021, we announced that we entered into an Ordinary Share Purchase Agreement with Aspire Capital Fund, LLC. Under the Agreement, Aspire has committed to purchase up to \$20 million of our ordinary shares at our discretion from time to time during a 30-month period at prices based on the market price at the time of each sale. We will retain full control as to the timing and amount of any sale of ordinary shares to Aspire, subject to certain limitations specified in the Purchase Agreement. There are no warrants or other derivative securities associated with the transaction. We have the right to terminate the Purchase Agreement at any time without any additional cost or penalty.

We commenced operations in 2000, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our VTS, MOSPD2 and Lecinoxoid platform technologies and developing our product candidates, including conducting preclinical studies for all three technologies and clinical trials of VB-111 and VB-201. To date, we have funded our operations through private sales of preferred shares, a convertible loan, public offering, revenues from licensing agreements and grants 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. 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 and through December 31, 2020, we had raised an aggregate of \$275.8 million to fund our operations, of which \$113.4 million was from sales of our equity securities, \$40.5 from our initial public offering, or IPO, \$15 million from a November 3, 2015 underwritten offering, approximately \$24.0 million from a June 7, 2016 registered direct offering, \$17.9 million from a November 16, 2017 underwritten offering, \$15.5 million from a June 27, 2018 registered direct offering, \$18.1 million from both a May 11, 2020 and May 13, 2020 registered direct offerings, \$28.8 million from IIA grants and \$2.6 million from at-the-market equity facility.

Since inception, we have incurred significant losses. For the years ended December 31, 2020, 2019 and 2018, our loss was \$24.2 million, \$19.4 million, and \$20.5 million, respectively. We expect to continue to incur significant expenses and losses for at least the next several years. As of December 31, 2020, we had an accumulated deficit of \$232.2 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, 2020, we had cash, cash equivalents, short-term bank deposits and restricted bank deposits of \$30.8 million. To fund further operations, we may need to raise additional capital. We may seek to raise more 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 March 1, 2021, we had 38 employees.

Financial Overview

Revenues and Cost of Revenues

Since inception, we generated cumulative revenues of approximately \$15.9 million revenue from exclusive license agreements for the development, commercialization, and supply of VB-111 in Japan for all indications and an option to license agreement for the development of VB-201 for animal healthcare worldwide. The generated revenues comprise upfront and milestone payments. The cost of revenues associated with these payments was approximately \$1.1 million. We do not expect to receive any other revenue from 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. For more detail on our revenue recognition treatment under US GAAP, refer to Note 1.m. to our Financial reports.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of our three platform technologies and our product candidates. 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 small-scale manufacturing facility;
- expenses incurred under agreements with CROs 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.

Research and development activities are the primary focus of our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Our research and development expenses may increase in absolute dollars in future periods as we continue to invest in research and development activities related to the development of our platform technologies and product candidates. In particular, our research and development expenses may increase as we develop VB-111 beyond ovarian cancer, and continue its clinical development in other oncology indications. In addition, our research and development expenses may increase as we develop our VB-600 series of product candidates.

Research 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, 2020, we did not have any capitalized development costs.

We have received grants from the IIA as part of the research and development programs for our VTS and Lecinoxoid platform technologies. 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, including VB-111 and VB-201. Under 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 generally cannot exceed 100% of the grants made to us, plus annual interest generally equal to the 12-month LIBOR applicable to dollar deposits, as published on the first business day of each calendar year. The total gross amount of grants actually received by us from the IIA, including accrued LIBOR interest as of December 31, 2020 and 2019, totaled \$36.0 million and \$33.4 million, respectively.

The Research Law is targeted at maintaining the intellectual property and manufacturing rights relating to IIA-funded projects in Israel. Under certain circumstances, where the above is not followed, the royalty rate might be higher and accordingly calculated to a formula based on the ratio of the participation by the State in the project to the total project costs incurred us.

In addition to paying any royalty due, we must abide by other restrictions associated with receiving such grants under the Research Law that continue to apply following repayment to the IIA. These restrictions may impair our ability to outsource manufacturing, 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. If we fail to comply with the Research Law, we may be subject to criminal charges.

Under applicable accounting rules, the grants income 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.

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, patent counseling and portfolio maintenance, consulting, auditing and accounting services.

Marketing Expenses

Marketing expenses consists principally of salaries and related cost for personnel in marketing and commercialization functions such as salaries, benefits and share-based compensation, in addition to commercialization consulting services.

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 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, 2020 of \$198.1 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.

The Company recognizes full valuation allowance since we do not expect taxable income.

Critical Accounting Policies and Significant Judgments and Estimates

This management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with US GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

We make estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

Revenue recognition

With respect to the License Agreement, the Company used its judgement in the following main issues:

Identifying the performance obligations in the agreement and determining whether the license provided is distinct - based on the Company’s 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 - the Company estimated the standalone selling prices of the services to be provided based on expected cost plus a margin and used the residual approach to estimate the standalone selling price of the license as the Company has 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. The Company determined that all such variable consideration shall be allocated to the license (the satisfied performance obligation).

Share-Based Compensation

With respect to grants to employees, the value of the labor services received from them in return is measured on the date of grant based on the fair value of the equity instruments granted to the employees.

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 the Company's equity (see also Note 9).

Clinical trial accruals

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 reflects the appropriate trial expense in the financial statements by matching the appropriate expenses with the period in which services and efforts are expended. As of December 31, 2020, the company had clinical accruals in the amount of approximately \$1.8 million.

Lease

In determining the lease term, we consider all facts and circumstances that create an economic incentive to exercise an extension option, or not exercise a termination option. Extension options are only included in the lease term if the lease is reasonably certain to be extended. At initial recognition of lease liability, we used incremental borrowing rate, which is the rate that the lessee would have to pay to borrow the funds necessary to obtain an asset of similar value in a similar economic environment with similar terms and conditions (see also Note 5).

Results of Operations

Comparison of Years Ended December 31, 2020, 2019 and 2018 (in thousands)

	Year ended December 31,			2020 Increase (Decrease)		2019 Increase (Decrease)	
	2020	2019	2018	\$	%	\$	%
Revenues	\$ 922	562	585	\$ 360	64%	\$ (23)	(4)%
Cost of Revenues	(394)	(222)	(255)	(172)	77%	33	(13)%
Gross profit	528	340	330	188	55%	10	3%
Expenses:							
Research and development, gross	\$ 21,125	\$ 17,460	\$ 17,193	\$ 3,665	21%	\$ 267	2%
Government grants	(1,469)	(2,746)	(2,015)	1,277	(47)%	(731)	36%
Research and development, net	\$ 19,656	\$ 14,714	\$ 15,178	\$ 4,942	34%	\$ (464)	(3)%
General and administrative	5,355	5,708	6,000	(353)	(6)%	(292)	(5)%
Marketing	-	-	397	-	0%	(397)	(100)%
Operating loss	24,483	20,082	21,245	4,401	22%	(1,163)	(5)%
Financial expense (income), net	(258)	(686)	(749)	428	(62)%	63	(8)%
Loss for the year	\$ 24,225	\$ 19,396	\$ 20,496	\$ 4,829	25%	\$ (1,100)	(5)%

Revenues

Revenues for the year ended December 31, 2020 were \$922 thousand, compared to \$562 thousand for the year ended in 2019 and \$585 thousand for the year ended December 31, 2018, an increase of \$360 thousand or 64% and a decrease of \$23 thousand or 4%, respectively.

The Cost of revenues for the year ended December 31, 2020 were \$394 thousand, compared to \$222 thousand for the year ended in 2019 and \$255 thousand for the year ended December 31, 2018. The cost of revenues is attributed to the labor costs and other expenses related to the performance obligations that were delivered during the period.

Research and development expenses, net

Research and development expenses are shown net of IIA grants. Research and development expenses, net for the year ended December 31, 2020 were \$19.7 million, compared to \$14.7 million for the year ended December 31, 2019 and \$15.2 million for the year ended December 31, 2018, an increase of \$4.9 million or 34% and a decrease of \$0.5 million, or 3%, respectively.

The increase in research and development expenses, net, in 2020 was comprised of an increase of MOSPD2 and Ovarian Phase III activity for approximately \$4.0 million in addition to a decrease in IIA grants received of approximately \$1.3 million, offset mainly by payroll related costs for share-based compensation expense of approximately \$0.3 million.

The decrease in research and development expenses, net, in 2019 was comprised of a decrease of approximately \$0.8 million in share-based compensation costs, a decrease in internal manufacturing and facility expenses at our own new manufacturing facility of approximately \$1.3 million for materials and maintenance, a decrease of \$4.3 million in costs incurred for the Phase 3 pivotal trial of VB-111 in rGBM that was at its peak activity in 2017 and ended in 2018 and an increase in the amounts of IIA grants received of \$0.7 million in 2019 for the VB-111 program, offset by an increase of about \$5.2 million in 2019 in the expenses for the Ovarian Phase 3 trial and \$1.3 million for further pipeline developments.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2020 were \$5.3 million, compared to \$5.7 million for the year ended December 31, 2019 and \$6.0 million for the year ended December 31, 2018, a decrease of \$0.4 million or 6%, and a decrease of \$0.3 million or 5%, respectively.

This decrease in 2020 is mainly attributed to share-based compensation expense and financial advisory costs. The decrease in 2019 is mainly attributed to share-based compensation expense.

Marketing expenses

No marketing expenses for the year ended December 31, 2020 and December 31, 2019. Marketing expenses for the year ended December 31, 2018 were \$0.4 million.

Financial expense (income), net

Financial expense (income), net for the year ended December 31, 2020 was (\$258) thousand, compared to (\$686) thousand for the year ended December 31, 2019, and (\$749) thousand for the year ended December 31, 2018, a decrease of \$428 thousand or 62% in income, and a decrease in income of \$63 thousand or 8%, respectively. The decrease in 2020 is mainly due lower interest rates received compared to 2019. The increase in 2019 is mainly due less favorable exchange rates in comparison to its preceding year.

Liquidity and Capital Resources

Since our inception and through December 31, 2020, we have raised a total of \$113.4 million from sales of our equity securities before the initial public offering, \$40.5 million gross in our initial public offering (\$34.9 million net), \$15.0 million from a November 3, 2015 underwritten offering (\$13.6 million net), \$24.0 million from a June 7, 2016 registered direct offering (\$21.9 million net), \$17.9 million from a November 16, 2017 underwritten offering, \$15.5 million from a June 27 registered direct offering, \$18.1 million from both a May 11, 2020 and May 13, 2020 registered direct offerings, \$28.8 million from IIA grants and \$2.6 million from at-the-market equity facility . Our primary uses of cash have been to fund working capital requirements and research and development, and we expect these will continue to represent our primary uses of cash. We intend to use our cash resources, together with the proceeds from the offerings described above, to advance clinical programs, working capital, and other general corporate purposes. We expect that our cash resources as of December 31, 2020 together with the additional cash from the exercise of outstanding warrants, ATM sales and share purchases by Aspire Capital after January 1, 2021, would provide sufficient funding for our operations into the fourth quarter of 2022.

On May 17, 2019, we entered into an Equity Distribution Agreement with Oppenheimer & Co. Inc., or Oppenheimer to offer and sell from time to time its ordinary shares, NIS 0.01 par value, having an aggregate offering price of up to \$15,000,000 through Oppenheimer acting as its agent and/or principal. For the year ended December 31, 2020, we sold an aggregate of 812,470 ordinary shares under our at-the-market equity facility. The total consideration amounted to \$1.0 million, net of issuance costs. Since January 1, 2021 through March 15, 2021, we have sold an aggregate of 1,285,366 ordinary shares under our at-the-market equity facility. The total consideration amounted to \$3.5 million net of issuance costs. In addition, subsequent to December 2020, we received additional cash from the exercise of 4,861,906 warrants from our May 2020 registered direct offerings for approximately \$7.0 million and from the share purchases of 800,000 shares from our January 14, 2021 ordinary share purchase agreement with Aspire Capital Fund, LLC. for approximately \$1.8 million.

Funding Requirements

On December 31, 2020, we had cash, cash equivalents, short-term bank deposits and restricted bank deposit of \$30.8 million and working capital of \$24.5 million. We expect that our cash and cash equivalents and short-term bank deposits together with the additional cash from the exercise of outstanding warrants, ATM sales and share purchases by Aspire Capital after January 1, 2021, would provide sufficient funding for our operations into the fourth quarter of 2022. We are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of VB-111 and our other product candidates. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory review of VB-111 and any other product candidates we may pursue;
- the costs of future development activities, including clinical trials, for VB-111 and any other product candidates we may pursue;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies; and
- our ability to establish any future collaboration arrangements on favorable terms, if at all.

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. We do not 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 technologies, future revenue streams or research programs 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 future commercialization efforts or grant rights to develop and market VB-111 and any other product candidates 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,		
	2020	2019	2018
	(in thousands)		
Cash used in operating activities	\$ (23,378)	\$ (13,089)	\$ (15,680)
Cash generated from (used in) investing activities	9,891	(6,100)	24,733
Cash provided by (used in) financing activities	17,067	(359)	13,671
Net increase (decrease) in cash and cash equivalents and restricted cash	\$ 3,580	\$ (19,548)	\$ 22,724

Operating Activities

Cash used in operating activities for the year ended December 31, 2020 was \$23.4 million and consisted of primarily net loss of \$24.2 million arising primarily from research and development activities in addition to working capital changes of \$2.1 million, partially offset by net aggregate non-cash charges of \$2.9 million, comprised mostly of share based compensation at fair value and depreciation.

Cash used in operating activities for the year ended December 31, 2019 was \$13.1 million and consisted of primarily net loss of \$19.4 million arising primarily from research and development activities, partially offset by a net reduction of working capital of \$1.6 million and net aggregate non-cash charges of \$3.7 million, comprised mostly of share based compensation at fair value and depreciation.

Cash used in operating activities for the year ended December 31, 2018 was \$15.7 million and consisted of primarily net loss of \$20.5 million arising primarily from research and development activities in addition to a net reduction of working capital of \$0.2 million, partially offset by net aggregate non-cash charges of \$5.3 million, comprised mostly of share based compensation at fair value and depreciation.

Investing Activities

Net cash generated from investing activities was \$9.9 million for the year ended December 31, 2020. This was primarily due to the maturity of short-term bank deposits.

Net cash used in investing activities was \$6.1 million for the year ended December 31, 2019. This was primarily due to the purchases of short-term bank deposits.

Net cash generated from investing activities was \$24.7 million for the year ended December 31, 2018. This was primarily due to the maturity of short-term bank deposits offset by the purchases of Property Plant & Equipment in relation to the new Modi'in facility.

Financing Activities

Net cash provided by financing activities was \$17.1 million for the year ended December 31, 2020 was mainly the result of the net receipt of \$16.4 million from the issuance of ordinary shares per the closing of the securities purchase agreements on May 7, 2020 and May 11, 2020.

Net cash used in financing activities was \$0.4 million for the year ended December 31, 2019 was the result of lease payments.

Net cash provided by financing activities was \$13.7 million for the year ended December 31, 2018 was the result of the net receipt of \$13.7 million from the issuance of ordinary shares per the closing of the June 28, 2018 underwritten offering.

Contractual Obligations and Commitments

We have obligations to make future payments to third parties that become due and payable on the achievement of certain development, regulatory and commercial milestones, such as the start of a clinical trial, filing of an NDA, approval by the FDA or product launch, or royalties upon sale of products. We have not included these commitments on our statements of financial position or in the table above because the achievement and timing of these milestones is not fixed and determinable. These potential future commitments include:

- *Agreement with the Contact Research Organization (CRO).* In January 2015, the Company entered into an agreement with a CRO according to which it will receive project management, clinical development and other related services from the CRO for the execution of the Phase 3 rGBM clinical trial study in consideration for up to \$18.7 million. Additional expenses related to changes in the study and in the estimated services involved were agreed upon and are being negotiated with the CRO during the execution of the study. Through December 31, 2020, expenses, comprised of the initial contract services plus the additional changes along the trial, in the total amount of \$22.0 million were incurred.
- *Agreements with the Contact Research Organizations (CROs).* In December 2017, the Company entered into agreements with a CROs according to which it will receive project management, clinical development and other related services from the CROs for the execution of the Phase 3 study in platinum-resistant ovarian cancer in consideration for approximately \$31.0 million. Through December 31, 2020, expenses in the total amount of \$13.5 million were incurred.
- *Agreement with Tel Hashomer.* On February 3, 2013, we entered into an agreement with Tel Hashomer-Medical Research, Infrastructure and Services Ltd., or Tel Hashomer, a private company whose purpose is to promote the welfare of the Sheba Medical Center, or the Hospital, and Prof. Dror Harats, our chief executive officer. The agreement with Tel Hashomer resolved claims of the Hospital regarding the ownership of certain inventions and patent rights owned by us and developed in part by Prof. Harats and other inventors who were engaged by us and by the Hospital in parallel. The agreement provided us with a waiver of rights by the Hospital and Tel Hashomer in connection with intellectual property developed by these inventors prior to the date of the agreement. In consideration for the waiver, we undertook to pay 1% of any net sales of any product covered by the intellectual property covered under the agreement, which includes all of our current product candidates, and 2% of any consideration that we receive for granting a license or similar rights to this intellectual property. Such amounts will be recorded as part of our 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, we are required to pay to Tel Hashomer 1% of the proceeds received by us or our shareholders as the case may be. In November 2014, following the completion of our IPO, we paid to Tel Hashomer the amount of \$0.4 million. In November 2017, we entered into a license agreement. For the cash payment received to date in this transaction, we paid Tel Hashomer an additional \$747 thousand royalty and all other payment obligations under this agreement will expire once we have 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.
- *Agreement with Janssen Vaccines & Prevention B.V.* On April 15, 2011, we entered into a Commercial License Agreement with Janssen Vaccines & Prevention B.V., or Janssen, for incorporating the adenovirus 5 in VB- 111 and other drug candidates for cancer for consideration including the following potential future payments:
 - an annual license fee of € 100,000 (\$123,000), 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 VB-111 or (ii) the termination of the agreement by us, which is permitted, upon three months' written advance notice to Janssen;
 - a milestone payment of € 400,000 (\$492,000) 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%-2.0% on net sales.
- In October 2016, we 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. The site houses the Company's local biological drugs manufacturing facility, headquarters, discovery research and clinical development. Through December 31, 2020, expenses in the total amount of approximately \$1.3 million were incurred.

There are no limits or caps on the amount of potential royalties. Pursuant to the agreement, the Company has the right to terminate the agreement by giving Janssen Vaccines & Prevention B.V. three months' written notice.

- Participation by the IIA. We receive grants from the IIA, as part of the oncology and anti-inflammatory research and development programs. The requirements and restrictions for such grants are set forth in the Research Law. These grants are subject to repayment through future royalty payments on sales of any products resulting from these research and development programs, including VB-111 and VB-201. Under the Research Law, we are obligated to pay royalties of 3% to 3.5%. The maximum aggregate royalties paid generally cannot exceed 100% of the grants made to us, plus annual interest generally equal to the 12-month LIBOR applicable to dollar deposits, as published on the first business day of each calendar year. The total gross amount of grants actually received by us from the IIA as of December 31, 2020 totaled approximately \$28.8 million, and the balance of the principal and interest in respect of our commitments for future payments to the IIA totaled approximately \$36.0 million license agreement. To date, we have paid the IIA in relation to our licenses agreement royalties of approximately \$0.5 million.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our statements of financial position.

Recently Issued and Adopted Accounting Pronouncements

The recent accounting pronouncements are set forth in Note 2 to our audited financial statements beginning on page F-1 of this Annual Report.

Safe Harbor

See “Cautionary Note Regarding Forward-Looking Statements” in the introduction to this Annual Report.

Item 6. Directors, Senior Management and Employees

Executive Officers and Directors

The following table sets forth certain information relating to our executive officers and directors, including their ages as of February 1, 2021. Unless otherwise stated, the address for our directors and executive officers is c/o Vascular Biogenics Ltd., 8 Hasatat St. Modi'in, Israel.

Name	Age	Position
Executive Officers and Director		
Dror Harats (3)	64	Chief Executive Officer and Director
Amos Ron	65	Chief Financial Officer and Company Secretary
Erez Feige	47	Vice President, Business Operations
Tami Rachmilewitz	51	Vice President, Clinical Development
Eyal Breitbart	54	Vice President, Research and Operations
Naamit Sher	66	Vice President, Drug Development
Ayelet Horn	50	General Counsel
Non-Executive Directors		
Bennett M. Shapiro (1)(3)(4)	81	Chairman and Director
Marc Kozin (1)(3)(4)	59	Vice Chairman and Director
Ruth Alon (2)(3)(4)	69	Director
Ruth Arnon (1)(4)	88	Director
Shmuel (Muli) Ben Zvi (1)(2)(4)	60	Director
Ron Cohen (3)(4)	65	Director
David Hastings (2)(4)	59	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

Prof. Dror Harats 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 is the Chairman of the Bert W. Strassburger Lipid Center and chair of the R&D division at the Chaim Sheba Medical Center at Tel Hashomer and chairman of its Institute Review Board. Prof. Harats received his M.D. from Hadassah Medical School at the Hebrew University of Jerusalem, Israel, following which he conducted post-doctoral work at the University of California, San Francisco. 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. Prof. Harats has also served as a visiting scientist at Syntax Discovery Research. Prof. Harats currently serves as an observer on the board of directors of Art Healthcare Ltd. 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.

Amos Ron has served as our chief financial officer since May 2011. Prior to joining our company, from July 2008 to April 2011, Mr. Ron was the chief financial officer of Atlantium Technologies Ltd., a privately held start-up in the field of clean-tech. Prior to that, Mr. Ron served as the chief financial officer and chief operating officer of Medical Compression Systems, and prior to that, Mr. Ron served as the chief financial officer of Interpharm Laboratories Group, a wholly owned subsidiary of Serono S.A. Mr. Ron holds an M.Sc. (Honors) in Chemical Technology Management from the Hebrew University of Jerusalem, a B.Sc. in Business Administration, Empire State College (SUNY) (Jerusalem Branch) and a B.Sc. in Chemistry from the Hebrew University of Jerusalem.

Dr. Erez Feige has served as our vice president of business operations since January 2014. Prior to that, from 2012 to 2014, Dr. Feige served as our director of business development and, from 2006 to 2012, Dr. Feige served as our head of biochemistry. Dr. Feige holds a B.Sc., and M.B.A. and a Ph.D. from Bar-Ilan University, Israel and completed a post-doctoral fellowship at the Dana-Farber Cancer Institute and Harvard Medical School.

Dr. Tami Rachmilewitz has served as our vice president of clinical development since June 2018. Prior to joining our company, from 2016 to 2018, Dr. Rachmilewitz served as Medical Director and Head of Pharmacovigilance for NeuroDerm, holding responsibility for all development aspects of clinical phase projects. Prior to that, from 2013 to 2016, she acted as Clinical Program Leader for Teva, leading a pivotal phase III trial in Multiple Sclerosis. From 2009 to 2013 she was a Clinical Development Medical Advisor for Novartis with expertise in Immunology. Dr. Rachmilewitz holds an M.D. from the Hadassah Medical School at the Hebrew University in Jerusalem, which is where she did her internship and residency in Psychiatry.

Dr. Eyal Breitbart has served as our vice president, research and operations since January 2014. Prior to that, from 2006 to 2013, Dr. Breitbart served as our vice president, research. Prior to that, Dr. Breitbart served as head of research from 2002 to 2006 and prior to that as project manager from 2001 to 2002. Dr. Breitbart holds a B.Sc., M.Sc. and Ph.D. from Bar-Ilan University, Israel, and completed a post-doctoral fellowship at Tufts University School of Medicine.

Dr. Naamit Sher has served as our vice president of drug development and regulatory affairs since 2006. Prior to joining our company, from 2005 to 2006, Dr. Sher was head of QC laboratories, operations division at Teva Pharmaceutical Industries Ltd. From 1992 to 2005, Dr. Sher acted as quality control/quality assurance director at InterPharm, a subsidiary of Ares-Serono. Dr. Sher holds a B.Sc., M.Sc. and Ph.D. from the Hebrew University of Jerusalem, Israel. She completed post-doctoral fellowships at each of the Hebrew University, Jerusalem, Israel, and Rutgers University.

Adv. Ayelet Horn has served as our general counsel since our inception in 2000, and has served as our company secretary between 2007 to 2016. Adv. Horn holds an LL.B from Tel-Aviv University, Israel, and an M.B.A. from Herriot Watt University, Edinburgh, Scotland.

Non-Executive Directors

Dr. Bennett M. Shapiro, M.D. has served on our board of directors since September 2004 and as Chairman since 2007. In addition to serving on our board of directors, Dr. Shapiro has been a senior partner at Puretech Ventures, an innovation enterprise, since 2004, and as chairman from 2009-2015; he continued as a Non-Executive Director of PureTech HealthPLC-PRTC until 2020. From 1990 to 2003, Dr. Shapiro served as executive vice president, Merck Research Laboratories. Prior to that, from 1970 to 1990, Dr. Shapiro was a professor of the Department of Biochemistry at the University of Washington and served as chairman from 1985 to 1990. Prior to joining the University of Washington, from 1965 to 1970 Dr. Shapiro served as a research associate, then section head, in the Laboratory of Biochemistry of the National Heart Institute of the U.S. National Institutes of Health. Dr. Shapiro has served as an external director on the board of directors of Momenta Pharmaceuticals from 2003-2016, various private companies, and the Drugs for Neglected Diseases Initiative, an independent, non-profit drug development partnership. Dr. Shapiro previously served on the board of directors of Celera Corporation prior to its acquisition by Quest Diagnostics Inc. Dr. Shapiro received his B.S. in chemistry from Dickinson College and his M.D. from Jefferson Medical College. Dr. Shapiro has been a Guggenheim Fellow, a fellow of the Japan Society for the Promotion of Science and a visiting professor at the University of Nice. We believe Dr. Shapiro is qualified to serve on our board of directors because of his extensive technical and industry background, and his experience serving on boards of directors of companies in our industry, including public companies.

Marc Kozin joined our board in October 2020 as Vice Chairman. Mr. Kozin has three decades of industry expertise advising biopharmaceutical, life sciences and medtech companies. He is currently the Chairman of the Strategy Advisory Board of HealthCare Royalty Partners (HCR), a leading investment firm in healthcare, providing royalty monetization and senior debt. 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. 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 over a dozen Boards in a variety of roles and on all committees. He is currently the Lead Independent Director and serves on the Compensation Committee of UFP Technologies (Nasdaq: UFPT). He serves as Director and Chairman of the Compensation Committee for Dicerna Pharmaceuticals (Nasdaq: DRNA). Previously, he served on the boards of Endocyte and Dyax. 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. He received a BS in Economics from Duke University in 1983 and an MBA in Finance from The Wharton School in 1987. We believe Mr. Kozin is qualified to serve on our board of directors because of his extensive industry and business background.

Prof. Ruth Arnon has served on our board of directors since August 2007. Prof. Arnon is an immunologist with the Weizmann Institute of Science in Israel. Prof. Arnon joined the staff of the Weizmann Institute in 1960, and served as vice president of the Institute from 1988 to 1997. Prof. Arnon is a member of the Israel Academy of Sciences, and from 2010 until 2015 served as its president. Prof. Arnon is also an elected member of the European Molecular Biology Organization. She has served as president of the European Federation of Immunological Societies, and as secretary-general of the International Union of Immunological Societies. Her awards and honors include the Robert Koch Prize in Medical Sciences, Spain's Jimenez Diaz Memorial Award, France's Legion of Honor, the Hadassah World Organization's Women of Distinction Award, the Wolf Prize for Medicine, the Rothschild Prize for Biology, and the Israel Prize. Prof. Arnon earned her M.Sc. in Chemistry from the Hebrew University, Jerusalem, Israel, and her Ph.D. from the Hebrew University. We believe Prof. Arnon is qualified to serve on our board of directors because of her extensive technical and industry background.

Ruth Alon has served on our board of directors since March 2010. Ms. Alon is currently the founder and CEO of Medstrada. Since 1997 and until December 24, 2016, Ms. Alon has served as a general partner in Pitango Venture Capital. Prior to her tenure at Pitango, Ms. Alon held senior positions with Montgomery Securities from 1981 to 1987, Genesis Securities, LLC from 1993 to 1996, and Kidder Peabody & Co. from 1987 to 1993, 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 (IATI), an umbrella organization of the hi-tech and life sciences industries in Israel, which includes venture capital funds, R&D centers of multinational corporations and others. 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.S. 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.

Dr. Ron Cohen, M.D. joined our board in February 2015. In addition to serving on our board of directors, Dr. Cohen has served as President, Chief Executive Officer and founder of Acorda Therapeutics, Inc., since 1995. Previously he was a principal in the startup and an officer of Advanced Tissue Sciences, Inc., a biotechnology company engaged in the growth of human organ tissues for transplantation, from 1986 to 1992. Dr. Cohen received his B.A. with honors in Psychology from Princeton University, and his M.D. from the Columbia College of Physicians & Surgeons. He completed his residency in Internal Medicine at the University of Virginia Medical Center, and is Board Certified in Internal Medicine. Dr. Cohen is a Director on the Board of the Biotechnology Innovation Organization (BIO) and previously served as Chair of the Board. He served as a Director of Dyax Corporation until the end of 2015, and also previously served as Director and Chair of the New York Biotechnology Association. He is a recipient of the NY CEO Lifetime Achievement Award and the Ernst & Young Entrepreneur of the Year Award for the New York Metropolitan Region, and has been recognized by PharmaVOICE Magazine as one of the 100 Most Inspirational People in the Biopharmaceutical Industry. We believe Dr. Cohen is qualified to serve on our board of directors because of his extensive business and industry background.

David Hastings joined our board in January 2018. Mr. Hastings has more than 20 years of finance, accounting and operations experience in the biopharmaceutical 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) 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. and Entasis, Inc. and chairs their Audit Committees. We believe Mr. Hastings is qualified to serve on our board of directors because of his extensive financial and business background.

Dr. Shmuel (Muli) Ben Zvi joined our board in September 2018. Dr. Ben Zvi is currently a board member at Bank Leumi, the second largest bank in Israel, risk management, information technologies and technological innovations, strategy, prospectuses, procedures and investments committees. Dr. Ben Zvi is also a board member of SOL-GEL Technologies (NASDAQ SLGL) and a member of the audit and compensation committees. From 2004 to 2014, Dr. Ben Zvi held various managerial positions at Teva Pharmaceuticals Industries Ltd., dual listed on Nasdaq and the TASE, including VP Finance and VP 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).

Arrangements Concerning Election of Directors; Family Relationships

Our current board of directors consists of eight directors.

We are not a party to, and are not aware of, any voting agreements among our shareholders. In addition, there are no family relationships among our executive officers and directors.

Advisory Boards

We established an advisory board with specific expertise in oncology. In addition, we have an advisory board comprised of industry experts with significant experience in the pharmaceutical industry.

Oncology Experts

Ovarian Cancer

Angeles Alvarez Secord, MD, Duke University
Rebecca C. Arend, MD, University of Alabama at Birmingham
Antonio Casado Herraiz, MD, PhD, Hospital Clínico San Carlos, Madrid, Spain
Thomas Herzog, MD, University of Cincinnati Cancer Institute
Jonathan A. Ledermann, MD, UCL Cancer Institute, UK
Bradley J. Monk, MD, FACS, FACOG, Univ. of Arizona & Creighton Univ.
Kathleen Moore, MD, University of Oklahoma Health Sciences Center
Richard T. Penson, MD, MRCP, Massachusetts General Hospital
Ronnie Shapira-Frommer, MD, Sheba Medical Center
Krishnansu S. Tewari, MD, University of California

Glioblastoma (GBM)

Andrew J. Brenner, MD, PhD, The University of Texas Health Science Center
Nicholas Butowski, MD, University of California
Timothy Cloughesy, MD, UCLA
Patrick Y. Wen, MD, Dana-Farber Cancer Institute

Additional Experts

Catrin Ball-Rosen
Marc Buyse, Sc.D.
Ronald Goldblum, M.D.
Melanie Hartsough, PhD
Susan Jerian, M.D.
Iftekhhar Mahmood, Ph.D
David Smolin, Ph.D.

Compensation of Executive Officers and Directors

The aggregate compensation paid by us to our current directors and executive officers, including share based compensation, for the year ended December 31, 2020, was \$3.6 million. This amount includes any amounts set aside or accrued to provide pension, severance, retirement, annual leave and recuperation or similar benefits or expenses. It does not include any business travel, relocation, professional and business association dues and expenses reimbursed to office holders, and other benefits commonly reimbursed or paid by companies in Israel. The above also includes the provision for bonuses for the year ended December 31, 2019 in the amount of \$0.4 million. As of December 31, 2020, options and RSU's to purchase an aggregate of 5,316,656 ordinary shares granted to our directors and executive officers were outstanding under the Employee Share Ownership and Option Plan (2000), or the 2000 Plan, and the Employee Share Ownership and Option Plan (2011), or the 2011 Plan, and the Employee Share Ownership and Option Plan (2014), or the 2014 Plan at a weighted average exercise price of \$2.24 per share.

Board of Directors

Under the Israeli Companies Law, 5759-1999, or the Companies Law, the management of our business is vested in our board of directors. Our board of directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our board of directors. Our chief executive officer is appointed by, and serves at the discretion of, our board of directors, subject to the employment agreement that we have entered into with him. All other executive officers are also appointed by our board of directors, and are subject to the terms of any applicable employment agreements that we may enter into with them.

Under our amended and restated articles of association, our board of directors must consist of at least three and not more than nine directors, including the external directors. Our board of directors currently consists of eight directors. Following the adoption by the Company of certain reliefs provided under the Companies Law, the Company is exempt from the requirement to appoint external directors and the individuals formerly appointed as external directors continue to serve as part of our board of directors until the end of their term and may be removed from office in the same manner as any other director. We have only one class of directors.

The following of our directors were elected in accordance with the terms of our articles of association in effect prior to the initial public offering of our shares on NASDAQ and are nominated for re-election by our shareholders at any consecutive annual general meeting:

- Dr. Shapiro was appointed as an industry expert by a majority of the other directors, a majority that included representatives of our major shareholders.
- Prof. Harats was entitled to be a board member for so long as Prof. Harats is either (i) the chief executive officer of our company; or (ii) a holder of 3% or more of our issued and outstanding share capital;
- Ms. Alon was originally appointed by persons affiliated with Pitango Venture Capital; Since 2017 Ms. Alon is not related to Pitango She was re-elected by the General Meeting of shareholders as an independent director.
- Prof. Ruth Arnon was appointed by a majority of the other directors, which included representatives of our major shareholders.

Upon the adoption of our amended and restated articles of association upon the closing of our initial public offering, the rights set forth in the previous articles were terminated and no additional agreements exist with respect to the nomination of our board members.

In accordance with the exemption available to certain Israeli public companies, whose shares are traded on NASDAQ, we chose as of November 7, 2016 not to follow the requirements of Companies Law with regard to the appointment of “external directors” as defined in the Companies Law, and instead, to follow the NASDAQ rules applicable to US domestic companies with respect to the appointment of independent directors. As long as we follow such reliefs, any reference to the election of our external directors in our amended articles of association shall have no actual expression.

We comply with NASDAQ rules that a majority of our directors are independent. Our board of directors has determined that with the exception of Prof. Harats, all of our directors are independent under such rules.

In accordance with the exemption available to foreign private issuers under NASDAQ rules, we do not intend to follow the requirements of NASDAQ rules with regard to the process of nominating directors, and instead, will follow Israeli law and practice, in accordance with which our board of directors (or a committee thereof) is authorized to recommend to our shareholders director nominees for election. See “Item 16G. Corporate Governance” for more information.

Under the Companies Law and our amended and restated articles of association, nominees for directors may also be proposed by any shareholder holding at least 1% of our outstanding voting power. However, any such shareholder may propose a nominee only if a written notice of such shareholder’s intent to propose a nominee has been given to our company secretary (or, if we have no such company secretary, our chief executive officer). Any such notice must include certain information, including, among other things, a description of all arrangements between the nominating shareholder and the proposed director nominee(s) and any other person pursuant to which the nomination(s) are to be made by the nominating shareholder, the consent of the proposed director nominee(s) to serve as our director(s) if elected and a declaration signed by the nominee(s) declaring that there is no limitation under the Companies Law preventing their election, and that all of the information that is required under the Companies Law to be provided to us in connection with such election has been provided.

In addition, our amended and restated articles of association allow our board of directors to appoint directors to fill vacancies on our board of directors, for a term of office equal to the remaining period of the term of office of the director(s) whose office(s) have been vacated.

Under the Companies Law, our board of directors must determine the minimum number of directors who are required to have accounting and financial expertise (as defined in the Companies Law). In accordance with the exemption available to certain Israeli public companies, whose shares are traded on NASDAQ, our board of directors elected not to follow the requirements of Companies Law with regard to the appointment of directors with accounting and financial expertise as defined in the Companies Law, and instead, to follow the NASDAQ rules applicable to US domestic companies with respect to the financial expertise of the directors. The exemption applies as long as the Company has no controlling shareholder, is in compliance with applicable US law and regulations and complies with the NASDAQ rules applicable to US domestic companies with respect to the appointment of independent directors and to the composition of the compensation and audit committees. Our board may further resolve at any time that we shall no longer follow the reliefs and in such event, we shall be required to appoint directors with accounting and financial expertise as defined in the Companies Law. Our board of directors has determined that the minimum number of directors who are required to have accounting and financial expertise is one.

External Directors

Under the Companies Law, a public company is required to have at least two directors who qualify as external directors. In accordance with the exemption available to certain Israeli public companies, whose shares are traded on NASDAQ and which do not have a controlling shareholder (the “Exemption to Foreign-listed Israeli Companies”), our board of directors elected not to follow the requirements of Companies Law with regard to the appointment of “external directors” as defined in the Companies Law, and instead, to follow the NASDAQ rules applicable to US domestic companies with respect to the appointment of independent directors. The exemption applies as long as the Company has no controlling shareholder, is in compliance with applicable US law and regulations and complies with the NASDAQ rules applicable to US domestic companies with respect to the appointment of independent directors and to the composition of the compensation and audit committees. Our board may further resolve at any time that we shall no longer follow the reliefs or determine that we are no longer in compliance with the requirements of such exemption, and in such event, we shall be required to appoint two directors as external directors.

Role of Board in Risk Oversight Process

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

Leadership Structure of the Board

In accordance with the Companies Law and our amended and restated articles of association, our board of directors is required to appoint one of its members to serve as chairman of the board of directors. Our board of directors has appointed Dr. Shapiro to serve as chairman of the board of directors.

Committees of the Board of Directors

We have an audit committee, a compensation committee and a nominating and corporate governance committee. We have adopted a charter for each of these committees.

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 US 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 Mr. David Hastings, Ms. Ruth Alon and Dr. 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 the Securities and Exchange Commission 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.

[Table of Contents](#)

Our board of directors has adopted an audit committee charter setting forth the responsibilities of the audit committee consistent with the rules of the Securities and Exchange Commission and NASDAQ rules as well as the requirements for such committee under the Companies Law, including the following:

- oversight of our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the board of directors in accordance with Israeli law;
- recommending the engagement or termination of the person filling the office of our internal auditor; and
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by our board of directors.

Our audit committee provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management.

Under the Companies Law, our audit committee is responsible for:

- determining whether there are deficiencies in our business management practices, including in consultation with our internal auditor or the independent auditor, and making recommendations to the board of directors to improve such practices;
- determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest) and whether such transaction is extraordinary or material under the Companies Law (see “-Approval of Related Party Transactions Under Israeli Law”);
- where the board of directors approves the work plan of the internal auditor, to examine such work plan before its submission to the board and propose amendments thereto;
- establishing the approval process for certain transactions with a controlling shareholder or in which a controlling shareholder has a personal interest;
- examining our internal controls and internal auditor’s performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities;
- examining the scope of our independent auditor’s work and compensation and submitting a recommendation with respect thereto to our board of directors or shareholders, depending on which of them is considering the appointment of our auditor; and
- establishing procedures for the handling of employees’ complaints as to deficiencies in the management of our business and the protection to be provided to such employees.

Our audit committee may not approve any actions requiring its approval (see- “Approval of Related Party Transactions Under Israeli Law”), unless at the time of approval a majority of the committee’s members are present, which majority consists of unaffiliated directors.

Compensation Committee

Our compensation committee consists of Dr. Ben Shapiro, of Marc Kozin, of Dr. Shmuel Ben-Zvi and of Dr. Ruth Arnon. Dr. Ben Shapiro serves as the chairman of the compensation committee. The members of our compensation committee are independent under the NASDAQ listing requirements.

Under the Companies Law, the board of directors of a public company must appoint a compensation 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 compensation committee, and instead, will follow the NASDAQ rules applicable to US domestic companies with respect to the appointment and composition of the compensation committee.

The duties of the compensation committee include the recommendation to our board of directors of a policy regarding the terms of engagement of office holders, to which we refer as a compensation policy. That policy must be adopted by the company's board of directors, after considering the recommendations of the compensation committee, and will need to be brought every three years for approval by the company's shareholders, which approval requires what we refer to as a special majority. A special majority approval requires shareholder approval by a majority vote of the shares present and voting at a meeting of shareholders called for such purpose, provided that either: (a) such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such compensation arrangement; or (b) the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in the compensation arrangement and who vote against the arrangement does not exceed 2% of the company's aggregate voting rights. On December 30, 2019, our shareholders approved our compensation policy for an additional three-year term.

Our compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must relate to certain factors, including advancement of the company's objectives, the company's business plan and its long term strategy, and creation of appropriate incentives for office holders. It must also consider, among other things, the company's risk management, size and nature of its operations. The term office holder is defined under the Companies Law as the general manager, chief executive officer, chief business manager, deputy general manager, vice general manager, any other person assuming the responsibilities of any of these positions regardless of that person's title, a director, or a manager directly subordinate to the general manager. The compensation policy must furthermore consider the following additional factors:

- the knowledge, skills, expertise, and accomplishments of the relevant office holder;
- the office holder's roles and responsibilities and prior compensation agreements with him or her;
- the relationship between the terms offered and the average compensation of the other employees of the company, including those employed through manpower companies;
- the impact of disparities in salary upon work relationships in the company;
- the possibility of reducing variable compensation at the discretion of the board of directors;
- the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and
- as to severance compensation, the period of service of the office holder, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contributions towards the company's achievement of its goals and the maximization of its profits, and the circumstances under which the person is leaving the company.

The compensation policy must also include the following principles:

- the link between variable compensation and long term performance and measurable criteria;
- the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation;
- the conditions under which an office holder would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;
- the minimum holding or vesting period for variable, equity-based compensation; and
- maximum limits for severance compensation.

The compensation committee is responsible for (a) recommending the compensation policy to a company's board of directors for its approval (and subsequent approval by its shareholders) and (b) duties related to the compensation policy and to the compensation of a company's office holders as well as functions previously fulfilled by a company's audit committee with respect to matters related to approval of the terms of engagement of office holders, including:

- recommending whether a compensation policy should continue in effect, if the then-current policy has a term of greater than three years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years);
- recommending to the board of directors periodic updates to the compensation policy;
- assessing implementation of the compensation policy; and
- determining whether the compensation terms of the chief executive officer of the company need not be brought to approval of the shareholders. Our board of directors has adopted a compensation committee charter setting forth the responsibilities of the committee, which include:
 - the responsibilities set forth in the compensation policy;
 - reviewing and approving the granting of options and other incentive awards to the extent such authority is delegated by our board of directors; and
 - reviewing, evaluating and making recommendations regarding the compensation and benefits for our non-employee directors.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Dr. Shapiro, Dr. Cohen, Mr. Marc Kozin, Ms. Alon and Prof. Harats and is chaired by Dr. Shapiro. Each of the members of our nominating and corporate governance committee, except for Prof. Harats are independent under the listing requirements of The NASDAQ Global Market.

Our board of directors has adopted a nominating and governance committee charter sets forth the responsibilities of the nominating and governance committee which include:

- overseeing and assisting our board in reviewing and recommending nominees for election as directors;
- assessing the performance of the members of our board; and
- establishing and maintaining effective corporate governance policies and practices, including, but not limited to, developing and recommending to our board a set of corporate governance guidelines applicable to our company.

Internal Auditor

Under the Companies Law, the board of directors of a public company must appoint an internal auditor based on the recommendation of the audit committee. The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. The audit committee is required to oversee the activities and to assess the performance of the internal auditor as well as to review the internal auditor's work plan. Our internal auditor is Mr. Zachi Refaeli from Ernst & Young Israel.

An internal auditor may not be:

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

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 and Directors” is 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. See “-Major Shareholders and Related Party Transactions” for a definition of controlling shareholder. 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.

Employment Agreements with Executive Officers and Directors

We have entered into written employment agreements with each of Dror Harats, Erez Feige, Amos Ron, Tami Rachmilewitz, Eyal Breitbart and Naamit Sher. All such agreements contain provisions regarding non-competition, confidentiality of information and assignment of inventions. The non-competition provisions apply for a period of 24 months following termination of the respective officer’s employment. In addition, we are required to provide notice of between three and six months prior to terminating the employment of such executive officers other than in the case of a termination for cause. Other than with respect to Prof. Harats, these agreements do not provide for benefits upon the termination of these executives’ respective employment with us, other than payment of salary and benefits during the required notice period for termination of these agreements, which varies under these individual agreements. Prof. Harats’s agreement provides for six months of severance in the event Prof. Harats’s employment is terminated by us without cause or terminated by Prof. Harats for good reason. Pursuant to his employment agreement, “Cause” means Prof. Harats’s conviction of any felony related to our business, a serious breach of trust by Prof. Harats, including theft, embezzlement of our funds, self-dealing, prohibited disclosure of confidential or proprietary information and Prof. Harats’s engagement in any prohibited business competitive to our own, Prof. Harats’s disregard of lawful instructions of our board of directors with respect to his duties to us following notice, or Prof. Harats’s willful failure to perform any of his fundamental functions or duties. Pursuant to his employment agreement, “Good reason” means a material reduction in Prof. Harats’s status, title, position or responsibilities, a reduction in Prof. Harats’s salary which is not part of a general reduction in salary applicable to all of our employees, a failure by us to continue any material compensation or benefit plan, program or practice in which Prof. Harats is participating, or a material breach by us of any provision of Prof. Harats’s employment agreement.

In addition, we have entered into compensation agreements with certain of our directors. The amounts payable pursuant to these arrangements have been approved by our board of directors and shareholders.

Our directors do not receive compensation for their service as our directors or otherwise, unless such compensation is approved by our compensation committee, and then by the board of directors followed by the shareholders. The compensation of our directors may be fixed, as an all-inclusive payment or as payment for participation in meetings, or as a combination thereof. In addition, such compensation may include: (i) in the case of a director who is also an officer, a salary or other compensation in respect of his or her work as an officer, as may be agreed upon by the director and us; and (ii) reimbursement of expenses, including travel expenses, expended in connection with his or her duties as a member of the board of directors.

Employees

As of March 1, 2021, we employed 38 employees, including 30 in research and development, and 8 in general and administrative positions, and of which 12 employees have either MDs or PhDs. All of our employees are located in Israel. We believe our employee relations are good.

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.

None of our employees currently work under any collective bargaining agreements.

Share Ownership

For information regarding the share ownership of our directors and executive officers, please refer to “-Equity Compensation Plans” below and “Item 7. Major Shareholders and Related Party Transactions-Major Shareholders.”

As of March 1, 2021, our directors and executive officers hold, in the aggregate, options, warrants and RSU’s outstanding for 5,348,588 ordinary shares.

These options have an average exercise price of \$2.22 per share and have expiration dates generally twenty years after the grant date of the option.

2,963,942 options and warrants are exercisable as of March 1, 2021 and have a weighted average exercise price of \$2.95 per share.

Equity Compensation Plans

The 2000 Plan, the 2011 Plan and the 2014 Plan, allow us to grant options to purchase our ordinary shares to our directors, officers, employees, consultants, advisers and service providers. The option plans are intended to enhance our ability to attract and retain desirable individuals by increasing their ownership interests in us. We no longer intend to grant options under the 2000 Plan or the 2011 Plan, and the remaining shares reserved for future grants under the option plans will constitute the initial share reserve for the 2014 Plan. Additionally, upon the expiration of options granted under the 2000 Plan or the 2011 Plan, the ordinary shares underlying such expired options will increase the pool reserved for allocation under the 2014 Plan. As of March 1, 2021, we had reserved an aggregate of 9,507,693 ordinary shares under the option plans. As of March 1, 2021, options and warrants to purchase an aggregate of 7,527,126 ordinary shares were outstanding and options to purchase 650,993 ordinary shares had been exercised.

The plans are designed to reflect the provisions of the Israeli Income Tax Ordinance [New Version]-1961, as amended, mainly Sections 102 and 3(i), of the Ordinance, which affords certain tax advantages to Israeli employees, officers and directors that are granted options in accordance with its terms.

Section 102 of the Ordinance allows employees, directors and officers, who are not controlling shareholders and who are Israeli residents, to receive favorable tax treatment for compensation in the form of shares or options. Section 102 of the Ordinance includes two alternatives for tax treatment involving the issuance of options or shares to a trustee for the benefit of the grantees and also includes an additional alternative for the issuance of options or shares directly to the grantee. Section 102(b)(2) of the Ordinance, which provides the most favorable tax treatment for grantees, permits the issuance to a trustee under the “capital gains track.” In order to comply with the terms of the capital gains track, all options granted under a specific plan and subject to the provisions of Section 102 of the Ordinance, as well as the shares issued upon exercise of such options and other shares received following any realization of rights with respect to such options, such as share dividends and share splits, must be registered in the name of a trustee selected by the board of directors and held in trust for the benefit of the relevant employee, director or officer. The trustee may not release these options or shares to the relevant grantee before the second anniversary of the registration of the options in the name of the trustee. However, under this track, we are not allowed to deduct an expense with respect to the issuance of the options or shares. Section 3(i) does not provide for a similar tax benefit.

The plans may be administered by our board of directors either directly or upon the recommendation of a committee appointed by our board of directors.

The compensation committee recommends to the board of directors, and the board of directors determines or approves the eligible individuals who receive options under the plans, the number of ordinary shares covered by those options, the terms under which such options may be exercised, and other terms and conditions of the options, all in accordance with the provisions of the plans. Option holders may not transfer their options except in the event of death or if the compensation committee determines otherwise. Our compensation committee or board of directors may at any time amend or terminate each of the plans; however, any amendment or termination may not adversely affect any options or shares granted under such plan prior to such action.

The option exercise price is determined by the compensation committee and specified in each option award agreement. In general, the option exercise price is the fair market value of the shares on the date of grant as determined in good faith by our board of directors.

Employee Share Ownership and Option Plan (2014)

In June 2014, we adopted and obtained shareholder approval for our 2014 Plan and the U.S. Appendix thereto. The 2014 Plan provides for the grant of options, restricted shares, restricted share units and other share-based awards to our directors, employees, officers, consultants, advisors and service providers, among others and to any other person whose services are considered valuable to us. Following the approval of the 2014 Plan by the Israeli tax authorities, we will only grant options or other equity incentive awards under the 2014 Plan, although previously-granted options and awards will continue to be governed by our 2000 Plan and 2011 Plan. The initial reserved pool under the 2014 Plan was 928,288 ordinary shares, and was adjusted as set forth in the 2014 Plan, including an automatic annual increase on January 1 of each year such that the number of shares issuable under the 2014 Plan will equal 4% of our issued and outstanding share capital on a fully diluted basis on each such January 1, or a lesser number of shares determined by the board of directors. As of March 1, 2021, the outstanding reserved pool under the 2014 Plan stands on 1,969,999.

The 2014 Plan is administered by our board of directors or by a committee designated by the board of directors, which shall determine, subject to Israeli law, the grantees of awards and the terms of the grant, including, exercise prices, vesting schedules, acceleration of vesting and the other matters necessary in the administration of the 2014 Plan. The 2014 Plan enables us to issue awards under various tax regimes including, without limitation, pursuant to Sections 102 and 3(i) of the Ordinance, and under Section 422 of the Code. Options granted under the 2014 Plan to U.S. residents may qualify as “incentive stock options” within the meaning of Section 422 of the Code, or may be non-qualified. The exercise price for “incentive stock options” must not be less than the fair market value on the date on which an option is granted, or 110% of the fair market value if the option holder holds more than 10% of our share capital.

We currently intend to grant awards under the 2014 Plan only to our employees, directors and officers who are not controlling shareholders and are considered Israeli residents, under the capital gains track of Section 102(b)2 of the Ordinance.

Awards under the 2014 Plan may be granted until June 8, 2034, 20 years from the date on which the 2014 Plan was approved by our board of directors, provided that awards granted to any U.S. participants may be granted until June 8, 2024, 10 years from the date on which the 2014 Plan was approved by our board of directors.

The options granted under the 2014 Plan generally vest over four years commencing on the date of grant such that 25% vest on the first anniversary of the date of grant and an additional 6.25% vest at the end of each subsequent three-month period thereafter for 36 months. Options, other than certain incentive share options, that are not exercised within 20 years from the grant date expire, unless otherwise determined by our board of directors or its designated committee, as applicable. Share options that qualify as “incentive stock options” granted to a person holding more than 10% of our voting power under the U.S. appendix to the 2014 Plan will expire within five years from the date of the grant and any other options granted under the U.S. appendix to the 2014 Plan will expire within 10 years from the date of grant. Except as otherwise determined by the board of directors or as set forth in an individual’s award agreement, in the event of termination of employment or services for reasons of disability or death, or retirement, the grantee, or in the case of death, his or her legal successor, may exercise options that have vested prior to termination within a period of one year from the date of disability or death, or within 180 days following retirement. If we terminate a grantee’s employment or service for cause, all of the grantee’s vested and unvested options will expire on the date of termination. If a grantee’s employment or service is terminated for any other reason, the grantee may exercise his or her vested options within 90 days of the date of termination. Any expired or unvested options return to the pool for reissuance.

In the event of a merger or consolidation of our company, or a sale of all, or substantially all, of our shares or assets or other transaction having a similar effect on us, then without the consent of the option holder, our board of directors may determine, at its absolute discretion, whether outstanding awards held by or for the benefit of any grantee and which have not yet vested, is to be assumed or substituted and whether acceleration of such awards will be available.

Employee Share Ownership and Option Plan (2011)

In April 2011, we adopted the 2011 Plan. The term of the 2011 Plan is twenty years. Each option granted under the 2011 Plan entitles the grantee to purchase our ordinary shares. The options granted under the 2011 Plan generally vest during a four-year period following the date of the grant in 13 installments: 25% of the options vest one year following the grant date, and additional 1/16 of the options vest at the end of each subsequent quarter over the course of the following three years. The options expire twenty years after the date of grant if not exercised earlier.

In the case of certain changes in our share capital structure, such as a consolidation or share split or dividend, appropriate adjustments will be made to the numbers of shares and exercise prices under outstanding options. Unless otherwise determined by the board of directors, upon the consummation of certain kinds of transactions, such as a liquidation, a merger, reorganization or sale of all or substantially all of our assets, any unexercised outstanding options shall expire, provided that in case of merger or consolidation or the sale, transfer or exchange of all or substantially all our assets or shares, the surviving corporation does not assume the options or substitute them with appropriate options in the surviving corporation.

In general, when an option holder's employment or service with us terminates, his or her option will no longer continue to vest following termination, and the holder may exercise any vested options for a period of 90 days following termination without cause. If an option holder's employment with us terminates due to disability (as determined by the board of directors) or if the termination of employment results from his or her death, then the option holder or his or her estate (as applicable) has twelve months to exercise the option. If an option holder retires from our company, then, with the approval of the board of directors, the option holder or his or her estate (as applicable) has six months to exercise the option. If termination of employment results from cause, his or her outstanding options will expire upon termination. No option may be exercised after its scheduled expiration date.

Employee Share Ownership and Option Plan (2000)

In February 2000, we adopted the 2000 Plan, which was amended and restated in 2003 due to changes in applicable tax law. The original term of the 2000 Plan was ten years. In 2013, the terms of outstanding options were extended by 10 years.

Each option granted under the 2000 Plan entitles the grantee to purchase one of our ordinary shares. The options granted under the 2000 Plan generally vest during a four-year period following the date of the grant in three installments: 50% of the options vest two years following the grant date, 25% of the options vest three years following the grant date and the remaining 25% of the options vest four years following the grant date. The options under the plan expire ten years after the date of grant if not exercised earlier.

In the case of certain changes in our share capital structure, such as a consolidation or share split or dividend, appropriate adjustments will be made to the numbers of shares and exercise prices under outstanding options. In the event of certain transactions, such as an acquisition, or a merger or reorganization or a sale of all or substantially all of our assets, there shall be an acceleration of exercise of unvested options, immediate or otherwise, which depends on, among other things, the nature of such transaction, and provided that in case of merger or consolidation the surviving corporation does not assume the options or substitute them with appropriate options in the surviving corporation.

In general, when an option holder's employment or service with us terminates, his or her option will no longer continue to vest following termination, and the holder may exercise any vested options for a period of 90 days following termination without cause. If an option holder's employment with us terminates due to disability (as determined by the board of directors) or if the termination of employment results from his or her death or due to retirement after age 60, then with the approval of the board of directors, the option holder or his or her estate (as applicable) has twelve months to exercise the option; however, the option may not be exercised after its scheduled expiration date. If termination of employment results from cause, his or her outstanding options will expire upon termination.

Item 7. Major Shareholders and Related Party Transactions

Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of February 1, 2021:

- 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 December 31, 2020 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 55,134,735 ordinary shares outstanding as of March 1, 2021.

According to our transfer agent, as of February 14, 2021 there were 12 record holders of our ordinary shares, of which two record holders were located in the United States. None of our shareholders has different voting rights from other shareholders.

Except as described in the footnotes below, we believe each shareholder has voting and investment power with respect to the ordinary shares indicated in the table as beneficially owned. Unless otherwise indicated, 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 Family Trust (1)	9,961,396	17.46%
Aurum Ventures M.K.I. Ltd (2)	6,839,059	12.13%
Victor Leo (3)	3,619,048	6.36%
Executive Officers and Directors		
Prof. Dror Harats (4)	2,002,142	3.55%
Dr. Bennett M. Shapiro	-	*
Prof. Ruth Arnon	-	*
Ms. Ruth Alon	-	*
Dr. Ron Cohen	-	*
Marc Kozin	-	*
David Hastings	-	*
Dr. Shmuel (Muli) Ben Zvi	-	*
Mr. Amos Ron	-	*
Dr. Erez Feige	-	*
Dr. Eyal Breitbart	-	*
Dr. Naamit Sher	-	*
Dr. Tamar Rachmilewitz	-	*
Adv. Ayelet Horn	-	*
All directors and executive officers as a group (14 individuals total)(5)	4,016,270	6.91%

* Less than 1%

- (1) Consists of (i) 3,959,865 ordinary shares held directly by Thai Lee (ii) 4,096,769 ordinary shares held by the Thai Lee Family Trust (the “Trust”) and (iii) 1,904,762 warrants to purchase ordinary shares exercisable as of March 1, 2021 held by the Trust. Thai Lee exercises voting and investment power over the Thai Lee Family Trust. As such, Ms. Lee may be deemed to have beneficial ownership over our shares held by the Thai Lee Family Trust. The 9,961,396 shares issuable upon the full exercise of a warrant. Such warrant is only exercisable to the extent that the holder thereof, together with its affiliates, would beneficially own no more than 19.99% of the outstanding ordinary after giving effect to such exercise (the “Lee Beneficial Ownership Limitation”). As a result of the Lee Beneficial Ownership Limitation, the number of shares that may be issued to the holder upon exercise of the warrant may change depending upon changes in the number of our outstanding ordinary shares. The address of the Thai Lee Family Trust is 290 Davidson Avenue Somerset, NJ 0887.
- (2) Consists of (i) 5,569,218 ordinary shares and (ii) 1,269,841 warrants to purchase ordinary shares exercisable as of March 1, 2021 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) 1,809,524 ordinary shares and (ii) 1,809,524 warrants to purchase ordinary shares exercisable as of March 1, 2021 held directly by Victor Leo. The address for Victor Leo is 70 Rainey Street, #3302, Austin, TX 78701.
- (4) Consists of (a) 723,801 outstanding shares held by or for Prof. Harats; (b) options to purchase 1,246,409 shares exercisable as of March 1, 2021; and (c) warrants for 31,932 shares exercisable as of March 1, 2021.
- (5) Consists of (a) options to purchase 2,932,010 shares exercisable as of March 1, 2021; (b) warrants for 31,932 shares exercisable as of March 1, 2021; and (c) 1,052,328 outstanding shares.

Related Party Transactions

The following is a description of the material terms of those transactions with related parties to which we are party since January 1, 2019.

On December 30, 2019, our shareholders approved the extension of our written compensation policy for an additional three-year term. We have adopted a written policy which provides that the approval of the audit committee is required to effect specified actions and transactions with our directors, executive officers and controlling shareholders, or in which such persons have an interest. See “Item 6. Directors, Senior Management and Employees-Approval of Related Party Transactions Under Israeli Law.” The term “controlling shareholder” means a shareholder with the ability to direct the activities of our company, other than by virtue of being an executive officer or director. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint the majority of the directors of the company or its general manager. For the purpose of approving transactions with controlling shareholders, as well as corporate approval of executive compensation, the term also includes any shareholder (or two or more shareholders having a personal interest in the same matter being brought for approval) that holds 25% or more of the voting rights of a company if the company has no shareholder that owns more than 50% of its voting rights. The transactions described below were entered into prior to the effectiveness of this policy.

Indemnification Agreements

We have in place indemnification agreements with each of our executive officers exculpating them from a breach of their duty of care to us to the fullest extent permitted by law, subject to limited exceptions, and undertaking to indemnify them to the fullest extent permitted by Israeli law, subject to limited exceptions, including with respect to liabilities resulting from the initial public offering to the extent such liabilities are not covered by insurance.

Employment Agreements

We have entered into employment agreements with our executive officers and key employees. The employment agreements contain standard provisions, including assignment of invention provisions and non-competition clauses. See “Item 6. Directors, Senior Management and Employees-Employment Agreements with Executive Officers.”

Item 8. Financial Information

Financial statements are set forth under Item 18.

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.

Item 9. The Offer and Listing

Our ordinary shares are quoted on the Nasdaq Global Market under the symbol “VBLT.”

Nasdaq Global Market

Our ordinary shares began trading on the Nasdaq Global Market under the symbol “VBLT” on October 1, 2014.

On March 13, 2021, the last reported sale price of our ordinary shares on the Nasdaq Global Market was \$1.64 per share.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Ordinary Shares

Voting

All ordinary shares will have identical voting and other rights in all respects.

Transfer of Shares

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

Election of Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for external directors described under “Item 6. Directors, Senior Management and Employees-Board of Directors.”

Under our amended and restated articles of association, our board of directors must consist of not less than three, not including two external directors, but no more than nine directors (including the external directors). Pursuant to our amended and restated articles of association, other than the external directors, for whom special election requirements apply under the Companies Law, the vote required to appoint a director is a simple majority vote of holders of our voting shares, participating and voting at the relevant meeting. Each director will serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal by a vote of the majority voting power of our shareholders at a general meeting of our shareholders or until his or her office expires by operation of law, in accordance with the Companies Law. In addition, our amended and restated articles of association allow our board of directors to appoint directors to fill vacancies on the board of directors to serve for a term of office equal to the remaining period of the term of office of the directors(s) whose office(s) have been vacated. External directors are elected for an initial term of three years, may be elected for additional terms of three years each under certain circumstances, and may be removed from office pursuant to the terms of the Companies Law. See “Item 6. Directors, Senior Management and Employees-Board of Directors.”

Dividend and Liquidation Rights

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

Pursuant to the Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, according to our then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of the distribution, or we may otherwise only distribute dividends that do not meet such criteria only with court approval. In each case, we are only permitted to distribute a dividend if our board of directors and the court, if applicable, determines that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

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

Shareholder Meetings

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be held no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to in our amended and restated articles of association as extraordinary general meetings. Our board of directors may call extraordinary general meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Companies Law provides that our board of directors is required to convene an extraordinary general meeting upon the written request of (i) any two of our directors or one-quarter of the members of our board of directors or (ii) one or more shareholders holding, in the aggregate, either (a) 5% or more of our outstanding issued shares and 1% of our outstanding voting power or (b) 5% or more of our outstanding voting power. One or more shareholders, holding 1% or more of the outstanding voting power, may ask the board to add an item to the agenda of a prospective meeting, if the proposal merits discussion at the general meeting.

[Table of Contents](#)

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may be between four and 40 days prior to the date of the meeting. Furthermore, the Companies Law requires that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

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

The Companies Law and our amended and restated articles of association require that a notice of any annual general meeting or extraordinary general meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

Under the Companies Law and our amended and restated articles of association, shareholders are not permitted to take action via written consent in lieu of a meeting.

Quorum Requirements

Pursuant to our amended and restated articles of association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. As a foreign private issuer, the quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or written ballot who hold or represent between them at least 25% of the total outstanding voting rights. A meeting adjourned for lack of a quorum is generally adjourned to the same day in the following week at the same time and place or to a later time or date if so specified in the notice of the meeting. At the reconvened meeting, any two or more shareholders present in person or by proxy shall constitute a lawful quorum.

Vote Requirements

Our amended and restated articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Companies Law or by our amended and restated articles of association. Under the Companies Law, each of (i) the approval of an extraordinary transaction with a controlling shareholder and (ii) the terms of employment or other engagement of the controlling shareholder of the company or such controlling shareholder's relative (even if not extraordinary) requires, the approval described above under "Management-Approval of Related Party Transactions Under Israeli Law-Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions." Under our amended and restated articles of association, the alteration of the rights, privileges, preferences or obligations of any class of our shares requires a simple majority vote of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting. An exception to the simple majority vote requirement is a resolution for the voluntary winding up, or an approval of a scheme of arrangement or reorganization, of the company pursuant to Section 350 of the Companies Law, which requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by voting deed and voting on the resolution.

Access to Corporate Records

Under the Companies Law, shareholders are provided access to: minutes of our general meetings; our shareholders register and principal shareholders register, articles of association and financial statements; and any document that we are required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Acquisitions Under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If (a) the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (b) the shareholders who did not accept the tender offer hold 2% or more of the issued and outstanding share capital of the company (or of the applicable class), the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This requirement does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if, as a result of the acquisition, the purchaser would become a holder of more than 45% of the voting rights in the company, provided that there is no other shareholder of the company who holds more than 45% of the voting rights in the company, subject to certain exceptions.

A special tender offer must be extended to all shareholders of a company, but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) outstanding shares representing at least 5% of the voting power of the company will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (excluding the purchaser, controlling shareholders, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, by a majority vote of each party's shareholders, and, in the case of the target company, a majority vote of each class of its shares, voted on the proposed merger at a shareholders meeting.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders (as described under "Item 6. Directors, Senior Management and Employees-Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions").

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders of the target company.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the merging entities, and may further give instructions to secure the rights of creditors.

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

Anti-takeover Measures

The Companies Law allow us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. No preferred shares are currently authorized under our amended and restated articles of association. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our amended and restated articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Companies Law as described above in "Voting Rights".

Tax Law

Israeli tax law treats some acquisitions, such as stock-for-stock swaps between an Israeli company and a foreign company, less favorably than U.S. tax law. For example, Israeli tax law may subject a shareholder who exchanges ordinary shares in an Israeli company for shares in a non-Israeli corporation to immediate taxation unless such shareholder receives authorization from the Israeli Tax Authority for different tax treatment.

Modification of Class Rights

Under the Companies Law and our amended and restated articles of association, the rights attached to any class of share, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our amended and restated articles of association.

Establishment

Our registration number with the Israeli Registrar of Companies is 51-289976-6. Our purpose as set forth in our amended and restated articles of association is to engage in any lawful activity.

Transfer Agent and Registrar

The transfer agent and registrar for our ordinary shares is American Stock Transfer & Trust Company, LLC.

C. Material Contracts

We have not entered into any material contracts other than in the ordinary course of business and other than those described in "Item 4. Information on the Company", "Item 6. Directors, Senior Management and Employees" or elsewhere in this Annual Report.

D. Exchange Controls

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of countries that are, or have been, in a state of war with Israel.

In 1998, Israeli currency control regulations were liberalized significantly, so that Israeli residents generally may freely deal in foreign currency and foreign assets, and non-residents may freely deal in Israeli currency and Israeli assets. There are currently no Israeli currency control restrictions on remittances of dividends on the ordinary shares or the proceeds from the sale of the shares provided that all taxes were paid or withheld; however, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

Non-residents of Israel may freely hold and trade our securities. Neither our articles of association nor the laws of the State of Israel restrict in any way the ownership or voting of ordinary shares by non-residents, except that such restrictions may exist with respect to citizens of countries which are in a state of war with Israel. Israeli residents are allowed to purchase our ordinary shares.

E. Taxation

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

Israeli Tax Considerations and Government Programs

The following is a brief summary of the material Israeli tax laws applicable to us, and certain Israeli Government programs that may benefit us. This section also contains a discussion of material Israeli tax consequences concerning the ownership and disposition of our ordinary shares purchased by investors. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of such investors include residents of Israel or traders in securities who are subject to special tax regimes not covered in this discussion. Because parts of this discussion are based on new tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion. The discussion below is subject to change, including due to amendments under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which change could affect the tax consequences described below.

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax, currently at the rate of 23% of a company's taxable income. However, the effective tax rate payable by a company that derives income from an Approved Enterprise, a Benefited Enterprise, a Preferred Enterprise or a Preferred Technology Enterprise (as discussed below) may be considerably less. Capital gains derived by an Israeli company are generally subject to tax at the prevailing corporate tax rate.

Law for the Encouragement of Industry (Taxes), 5729-1969

The Law for the Encouragement of Industry (Taxes), 5729-1969, generally referred to as the Industry Encouragement Law, provides several tax benefits for "Industrial Companies."

The Industry Encouragement Law defines an "Industrial Company" as a company incorporated and resident in Israel, of which 90% or more of its income in any tax year, other than income from defense loans, is derived from an "Industrial Enterprise" owned by it that is located in Israel. An "Industrial Enterprise" is defined as an enterprise whose principal activity in a given tax year is industrial production.

The following corporate tax benefits, among others, are available to Industrial Companies:

- amortization over an eight-year period of the cost of patents and rights to use patents and know-how which were purchased in good faith and are used for the development or advancement of the Industrial Enterprise;
- under certain conditions, an election to file consolidated tax returns with related Israeli Industrial Companies; and
- expenses related to a public offering are deductible in equal amounts over three years.

There is no assurance that we qualify as an Industrial Company or that the benefits described above are currently available to us or will be available to us in the future.

Law for the Encouragement of Capital Investments, 5719-1959

The Law for the Encouragement of Capital Investments, 5719-1959, generally referred to as the Investment Law, provides certain incentives for capital investments in productive assets, such as production facilities, by "Industrial Enterprises" (as defined under the Investment Law).

The Investment Law was significantly amended effective April 1, 2005 (the "2005 Amendment"), and further amended as of January 1, 2011 (the "2011 Amendment") and as of January 1, 2017 (the "2017 Amendment"). Pursuant to the 2005 Amendment, tax benefits granted in accordance with the provisions of the Investment Law prior to its revision by the 2005 Amendment remain in force but any benefits granted subsequently are subject to the provisions of the 2005 Amendment. Similarly, the 2011 Amendment introduced new benefits to replace those granted in accordance with the provisions of the Investment Law in effect prior to the 2011 Amendment. However, companies entitled to benefits under the Investment Law as in effect prior to January 1, 2011 were entitled to choose to continue to enjoy such benefits, provided that certain conditions are met, or elect instead, irrevocably, to forego such benefits and have the benefits of the 2011 Amendment apply. Finally, the 2017 Amendment provided another benefits track, which represents an alternative to the tracks available under the 2005 Amendment and the 2011 Amendment. We have examined the possible effect, if any, of these provisions of the 2011 Amendment and the 2017 Amendment on our financial statements and have decided, at this time, not to opt to apply the new benefits under the 2011 Amendment or the 2017 Amendment.

Tax Benefits Prior to the 2005 Amendment

An investment program that is implemented in accordance with the provisions of the Investment Law prior to the 2005 Amendment, referred to as an "Approved Enterprise," is entitled to certain benefits. A company that wished to receive benefits as an Approved Enterprise must have received approval from the Investment Center of the Israeli Ministry of the Economy (formerly the Ministry of Industry, Trade and Labor), or the Investment Center. Each certificate of approval for an Approved Enterprise relates to a specific investment program in the Approved Enterprise, delineated both by the financial scope of the investment and by the physical characteristics of the facility or the asset.

In general, an Approved Enterprise is entitled to receive a grant from the Government of Israel or an alternative package of tax benefits, known as the alternative benefits track. The tax benefits from any certificate of approval relate only to taxable income attributable to the specific Approved Enterprise. Income derived from activity that is not integral to the activity of the Approved Enterprise does not enjoy tax benefits.

In addition, a company that has an Approved Enterprise program is eligible for further tax benefits if it qualifies as a Foreign Investors' Company ("FIC"), which is a company with a level of foreign investment, as defined in the Investment Law, of more than 25%. The level of foreign investment is measured as the percentage of rights in the company (in terms of shares, rights to profits, voting and appointment of directors), and of combined share capital and loans, that are owned, directly or indirectly, by persons who are not residents of Israel. The determination as to whether a company qualifies as an FIC is made on an annual basis.

If a company elects the alternative benefits track and distributes a dividend out of income derived by its Approved Enterprise during the tax exemption period it will be subject to corporate tax in respect of the amount of the dividend (grossed-up to reflect the pre-tax income that it would have had to earn in order to distribute the dividend) at the corporate tax rate which would have been applicable without the tax exemption under the alternative benefits track. In addition, dividends paid out of income attributed to an Approved Enterprise are generally subject to withholding tax at source at the rate of 15% or such lower rate as may be provided in an applicable tax treaty.

The Investment Law also provides that an Approved Enterprise is entitled to accelerated depreciation on its property and equipment that are included in an Approved Enterprise program during the first five years in which the equipment is used.

The benefits available to an Approved Enterprise are subject to the fulfillment of conditions stipulated in the Investment Law and its regulations and the criteria in the specific certificate of approval. If a company does not meet these conditions, it would be required to repay the amount of tax benefits, as adjusted by the Israeli consumer price index, and interest.

We do not have Approved Enterprise programs.

Tax Benefits Subsequent to the 2005 Amendment

The 2005 Amendment applies to new investment programs commencing after 2004, but does not apply to investment programs approved prior to April 1, 2005. The 2005 Amendment provides that terms and benefits included in any certificate of approval that was granted before the 2005 Amendment became effective (April 1, 2005) will remain subject to the provisions of the Investment Law as in effect on the date of such approval.

The 2005 Amendment provides that a certificate of approval from the Investment Center will only be necessary for receiving cash grants. As a result, it was no longer necessary for a company to obtain an Approved Enterprise certificate of approval in order to receive the tax benefits previously available under the alternative benefits track. Rather, a company may claim the tax benefits offered by the alternative benefits track directly in its tax returns, provided that it meets the criteria for tax benefits set forth in the amendment. In order to receive the tax benefits, the 2005 Amendment states, *inter alia*, that a company must make an investment which meets all of the conditions, including a minimum qualifying investment in certain productive assets as specified in the Investment Law. Such investment, along with the fulfillment of certain export requirements, allows a company to receive "Benefited Enterprise" status, and may be made over a period of no more than three years culminating with the end of the Benefited Enterprise election year.

The extent of the tax benefits available under the 2005 Amendment to qualifying income of a Benefited Enterprise depends on, among other things, the geographic location in Israel of the Benefited Enterprise. The location will also determine the period for which tax benefits are available. Such tax benefits include an exemption from corporate tax on undistributed income generated by the Benefited Enterprise for a period of between two to ten years, depending on the geographic location of the Benefited Enterprise in Israel, and a reduced corporate tax rate of between 10% to 25% for the remainder of the benefits period, depending on the level of foreign investment in the company in each year. The benefits period is limited to 12 years from the beginning of the Benefited Enterprise election year. With respect to an establishment Benefited Enterprise plan located in certain specific locations, the benefits period is limited to 14 years from the beginning of the Benefited Enterprise election year, depending on the location of the Benefited Enterprise. We informed the Israeli Tax Authority of our choice of 2012 as a Benefited Enterprise election year. A company qualifying for tax benefits under the 2005 Amendment which pays a dividend out of income derived by its Benefited Enterprise during the tax exemption period will be subject to corporate tax in respect of the amount of the dividend (grossed-up to reflect the pre-tax income that it would have had to earn in order to distribute the dividend) at the corporate tax rate which would have otherwise been applicable. Dividends paid out of income attributed to a Benefited Enterprise are generally subject to withholding tax at source at the rate of 15% or such lower rate as may be provided in an applicable tax treaty.

The benefits available to a Benefited Enterprise are subject to the fulfillment of conditions stipulated in the Investment Law and its regulations. If a company does not meet these conditions, in a given tax year during the benefits period, it would generally not be eligible for tax benefits during such tax year; however, the company's eligibility for tax benefits in prior and future years should not be impacted.

We currently have one Benefited Enterprise program under the Investments Law, which, we believe, may entitle us to certain tax benefits. The tax benefit period for this program has not yet commenced but is expected to end no later than the end of tax year 2023. During the benefits period, which shall commence with the year we will first earn taxable income relating to such enterprise, subject to the 12 years limitation described above, and shall run for a period of up to 10 years (assuming FIC status), a corporate tax exemption is expected to apply with respect to the taxable income from our Benefited Enterprise program (once generated) generated during the first two years of the benefits period (so long as it remains undistributed) and reduced corporate tax rates are expected to apply to such taxable income generated in the remaining years of the benefits period.

There is no assurance that our future taxable income will qualify as Benefited Enterprise income or that the benefits described above will be available to us in the future.

Tax Benefits Under the 2011 Amendment

The 2011 Amendment canceled the availability of the benefits granted to companies under the Investment Law prior to 2011, subject to certain exceptions, and, instead, introduced new benefits for income generated by a “Preferred Company” through its “Preferred Enterprise” (as such terms are defined in the Investment Law) as of January 1, 2011. The definition of a Preferred Company includes a company incorporated in Israel that is not wholly-owned by a governmental entity, and that has, among other things, Preferred Enterprise status and is controlled and managed from Israel. Pursuant to the 2011 Amendment, in 2014 and thereafter a Preferred Company is entitled to a reduced corporate tax rate of 16% with respect to its income derived by its Preferred Enterprise unless the Preferred Enterprise is located in development zone A, in which case the rate will be 9%. This latter rate was reduced to 7.5% as of January 1, 2017. It should be noted that the classification of income generated from the provision of usage rights in know-how or software that were developed in the Preferred Enterprise, as well as royalty income received with respect to such usage, as Preferred Enterprise income may be subject to the issuance of a pre-ruling from the Israel Tax Authority stipulating that such income is associated with the productive activity of the Preferred Enterprise in Israel.

Dividends paid out of income attributed to a Preferred Enterprise are generally subject to withholding tax at source at the rate of 20% or such lower rate as may be provided in an applicable tax treaty. However, if such dividends are paid to an Israeli company, no tax is required to be withheld (although, if such dividends are subsequently distributed to individuals or a non-Israeli company, withholding tax at a rate of 20% or such lower rate as may be provided in an applicable tax treaty will apply).

The 2011 Amendment also provided transitional provisions to address companies that may be eligible for tax benefits under the Approved Enterprise or Benefited Enterprise regimes. These transitional provisions provide, among other things, that unless an irrevocable request is made to apply the provisions of the Investment Law as amended in 2011 with respect to income to be derived as of January 1, 2011: (1) the terms and benefits included in any certificate of approval that was granted to an Approved Enterprise which chose to receive grants before the 2011 Amendment became effective will remain subject to the provisions of the Investment Law as in effect on the date of such approval, and subject to certain other conditions, (2) terms and benefits included in any certificate of approval that was granted to an Approved Enterprise which had participated in an alternative benefits track before the 2011 Amendment became effective will remain subject to the provisions of the Investment Law as in effect on the date of such approval, provided that certain conditions are met, and (3) a Benefited Enterprise can elect to continue to benefit from the benefits provided to it before the 2011 Amendment came into effect, provided that certain conditions are met.

We have examined the potential Israeli tax implications associated with the adoption and implementation of the provisions of the 2011 Amendment and have decided, at this time, not to apply the new benefits under the 2011 Amendment. There is no assurance that our future taxable income will qualify as Preferred Enterprise income or that the benefits described above will be available to us in the future.

The termination or substantial reduction of any of the benefits available under the Investment Law could materially increase our tax liabilities.

Tax Benefits Under the 2017 Amendment

The 2017 Amendment introduced new benefits for income generated by a “Preferred Company” (as defined above) through its “Preferred Technology Enterprise” (as defined in the Investment Law) as of January 1, 2017. Pursuant to the 2017 Amendment, in 2017 and thereafter a Preferred Company is entitled to a reduced corporate tax rate of 12% with respect to its income derived by its Preferred Technology Enterprise unless the Preferred Enterprise is located in development zone A, in which case the rate will be 7.5%. It should be noted that the calculation of a Preferred Company’s Preferred Technology Enterprise income is based on a complex formula and the income not classified as such may be classified as Preferred Enterprise income or ordinary income depending on the circumstances. In addition, a Preferred Company must generally fulfill certain conditions to be eligible for Preferred Technology Enterprise status including, *inter alia*, an R&D expenses level of at least 7% of total revenues or NIS 75 million per year.

Dividends paid out of Preferred Technology Enterprise income are generally subject to withholding tax at source at the rate of 20% or such lower rate as may be provided in an applicable tax treaty. However, subject to the fulfillment of certain conditions, to the extent that the dividends are paid to a direct foreign parent company holding at least 90% of the shares of the Preferred Company, a reduced withholding tax rate of 4% shall apply. Notwithstanding the above, if such dividends are paid to an Israeli company, no tax is required to be withheld (although, if such dividends are subsequently distributed to individuals or a non-Israeli company, withholding tax at a rate of 20% or such lower rate as may be provided in an applicable tax treaty will apply).

We have examined the potential Israeli tax implications associated with the adoption and implementation of the provisions of the 2017 Amendment and have decided, at this time, not to apply the new benefits under the 2017 Amendment. There is no assurance that our future taxable income will qualify as Preferred Technology Enterprise income or that the benefits described above will be available to us in the future.

The termination or substantial reduction of any of the benefits available under the Investment Law could materially increase our tax liabilities.

Taxation of Our Shareholders

This discussion does not address the tax consequences applicable to shareholders that own, or have owned at any time, directly or indirectly, 10% or more of our shares (“Controlling Shareholders”), and such shareholders should consult their tax advisers as to the tax consequences of owning or disposing of our shares.

Capital Gains Taxes Applicable to Non-Israeli Resident Shareholders

A non-Israeli resident who derives capital gains from the sale of shares in an Israeli resident company that were purchased after the Company was listed for trading on a stock exchange outside of Israel will be exempt from Israeli tax so long as, *inter alia*, such capital gains were not attributable to a permanent establishment that the non-resident maintains in Israel.

However, non-Israeli resident corporations will not be entitled to the foregoing exemption if the Israeli residents: (i) have a controlling interest, directly or indirectly, alone, together with another (i.e., together with a relative, or together with someone who is not a relative but with whom, according to an agreement, there is regular cooperation in material matters of the company, directly or indirectly), or together with another Israeli resident, of more than 25% in one or more of the means of control in such non-Israeli resident corporation, or (ii) Israeli residents are the beneficiaries of, or are entitled to, 25% or more of the revenues or profits of such non-Israeli resident corporation, whether directly or indirectly.

Additionally, a sale of securities by a non-Israeli resident may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty. For example, under the United States- Israel Tax Treaty, the disposition of shares by a shareholder who (1) is a U.S. resident (for purposes of the treaty), (2) holds the shares as a capital asset, and (3) is entitled to claim the benefits afforded to such person by the treaty, is generally exempt from Israeli capital gains tax. Such exemption will not apply if: (1) the capital gain arising from the disposition can be attributed to a permanent establishment in Israel, (2) the shareholder holds, directly or indirectly, shares representing 10% or more of the voting power of the company during any part of the 12-month period preceding the disposition, subject to certain conditions, or (3) such U.S. resident is an individual and was present in Israel for 183 days or more during the relevant taxable year. In such case, the sale, exchange or disposition of our ordinary shares would be subject to Israeli tax, to the extent applicable; however, under the United States-Israel Tax Treaty, the taxpayer would be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange or disposition, subject to the limitations under U.S. law applicable to foreign tax credits. The United States-Israel Tax Treaty does not relate to U.S. state or local taxes.

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

Taxation of Non-Israeli Shareholders on Receipt of Dividends

Non-Israeli residents are generally subject to Israeli withholding tax on the receipt of dividends paid on our ordinary shares at the rate of 25%, unless relief is provided in a treaty between Israel and the shareholder’s country of residence, subject to receipt of a valid certificate from the Israeli Tax Authority allowing for such reduced rate. With respect to a person who is a “substantial shareholder” at the time of receiving the dividend or at any time during the preceding twelve months, the applicable withholding tax rate is 30%. Furthermore, an additional 3% tax might be applicable to individual shareholders if certain conditions are met. A “substantial shareholder” is generally a person who alone or together with such person’s relative or another person who collaborates with such person on a permanent basis, holds, directly or indirectly, at least 10% of any of the “means of control” of the corporation. “Means of control” generally include the right to vote, receive profits, nominate a director or an executive officer, receive assets upon liquidation, or order someone who holds any of the aforesaid rights how to act, regardless of the source of such right. Notwithstanding the above, dividends paid to a non-Israeli resident “substantial shareholder” on publicly traded shares, like our ordinary shares, which are held via a “nominee company” (as defined under the Securities Law, 1968), are generally subject to Israeli withholding tax at a rate of 25%, unless a different rate is provided under an applicable tax treaty, provided that a certificate from the Israeli Tax Authority allowing for a reduced withholding tax rate is obtained in advance. Under the United States-Israel Tax Treaty, the maximum rate of tax withheld at source in Israel on dividends paid to a holder of our ordinary shares who is a U.S. resident (for purposes of the United States- Israel Tax Treaty) is 25%. Unless a reduced tax rate is provided under an applicable tax treaty, a distribution of dividends to non-Israeli residents is subject to withholding tax at source at a rate of 15% if the dividend is distributed from income attributed to an Approved Enterprise or a Benefited Enterprise, while a 20% rate applies if the dividend is distributed from Preferred Enterprise income or Preferred Technology Enterprise income (unless the dividend is paid to a foreign parent company directly holding at least 90% of the shares of the Preferred Company, in which case a 4% withholding tax rate shall apply). We cannot assure you that in the event we declare a dividend we will designate the income out of which the dividend is paid in a manner that will reduce shareholders’ tax liability.

If the dividend is attributable partly to Approved Enterprise income, Benefited Enterprise income, Preferred Enterprise income or Preferred Technology Enterprise income, and partly to other sources of income, the withholding rate will be a blended rate reflecting the relative portions of the two types of income. U.S. residents who are subject to Israeli withholding tax on a dividend may be entitled to a credit or deduction for United States federal income tax purposes in the amount of the taxes withheld, subject to detailed rules contained in U.S. tax legislation.

Estate and Gift Tax

Israeli law presently does not impose estate or gift taxes.

Certain Material U.S. Federal Income Tax Considerations

The following is a description of the material U.S. federal income tax considerations relating to the ownership and disposition of our ordinary shares by a U.S. Holder (as defined below). This description addresses only the U.S. federal income tax considerations to U.S. Holders that will hold such ordinary shares as capital assets. This description does not address tax considerations applicable to U.S. Holders that may be subject to special tax rules, including, without limitation:

- banks, financial institutions or insurance companies;
- real estate investment trusts, regulated investment companies or grantor trusts;
- brokers, dealers or traders in securities, commodities or currencies;
- tax exempt entities or organizations, including an “individual retirement account” or “Roth IRA” as defined in Section 408 or 408A of the Code (as defined below), respectively;
- certain former citizens or long term residents of the United States;
- persons that received our shares as compensation for the performance of services;
- persons that will hold our shares as part of a “hedging,” “integrated” or “conversion” transaction or as a position in a “straddle” for U.S. federal income tax purposes;
- partnerships (including entities classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or holders that will hold our shares through such an entity;
- S corporations;
- persons that acquire ordinary shares as a result of holding or owning our preferred shares;
- persons whose “functional currency” is not the U.S. dollar; or
- persons that own directly, indirectly or through attribution 10% or more of the voting power or value of our shares.

Moreover, this description does not address the U.S. federal estate, gift, or alternative minimum tax considerations, or any U.S. state, local or non-U.S. tax considerations of the ownership and disposition of our ordinary shares.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, changes to the code based on the U.S. tax reform (as described below) existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, in each case as in effect and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the U.S. Internal Revenue Service, or the IRS, will not take a different position concerning the tax consequences of the ownership and disposition of our ordinary shares or that such a position would not be sustained. Holders should consult their own tax advisers concerning the U.S. federal, state, local and foreign tax consequences of owning and disposing of our ordinary shares in their particular circumstances.

For purposes of this description, the term “U.S. Holder” means a beneficial owner of our ordinary shares that, for U.S. federal income tax purposes, is (i) a citizen or resident of the United States, (ii) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax regardless of its source, or (iv) a trust with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions.

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds our ordinary shares, the U.S. federal income tax consequences relating to an investment in our ordinary shares will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax considerations of acquiring, owning and disposing of our ordinary shares in its particular circumstances.

As indicated below, this discussion is subject to U.S. federal income tax rules applicable to a “passive foreign investment company,” or a PFIC.

Persons considering an investment in our ordinary shares should consult their own tax advisors as to the particular tax consequences applicable to them relating to the ownership and disposition of our ordinary shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Distributions

Subject to the discussion under “-Passive Foreign Investment Company Considerations,” below, if you are a U.S. Holder, the gross amount of any distribution made to you with respect to our ordinary shares before reduction for any Israeli taxes withheld therefrom, other than certain distributions, if any, of our ordinary shares distributed pro rata to all our shareholders, generally will be includible in your income as dividend income to the extent such distribution is paid out of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. To the extent that the amount of any distribution by us exceeds our current and accumulated earnings and profits as determined under U.S. federal income tax principles, it will generally be treated first as a return of your adjusted tax basis in our ordinary shares and thereafter as either long-term or short-term capital gain depending upon whether the U.S. Holder has held our ordinary shares for more than one year as of the time such distribution is received. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles. Therefore, U.S. Holders should expect that the entire amount of any distribution generally will be reported as dividend income. Non-corporate U.S. Holders may qualify for the preferential rates of taxation with respect to dividends on ordinary shares applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to qualified dividend income (as discussed below). The Company, which is incorporated under the laws of the State of Israel, believes that it qualifies as a resident of Israel for purposes of, and is eligible for the benefits of, the Convention between the Government of the United States of America and the Government of the State of Israel with Respect to Taxes on Income, signed on November 20, 1975, as amended and currently in force, or the U.S.-Israel Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-Israel Tax Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. Therefore, subject to the discussion under “-Passive Foreign Investment Company Considerations,” below, if the U.S.-Israel Tax Treaty is applicable, such dividends will generally be “qualified dividend income” in the hands of individual U.S. Holders, provided that certain conditions are met, including holding period and the absence of certain risk reduction transaction requirements are met. The dividends will not be eligible for the dividends received deduction generally allowed to corporate U.S. Holders.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or the TCJA. The TCJA provides a 100% deduction for the foreign-source portion of dividends received after January 1, 2018 from “specified 10-percent owned foreign corporations” by U.S. corporate holders, subject to a one-year holding period. No foreign tax credit, including Israeli withholding tax (or deduction for foreign taxes paid with respect to qualifying dividends) would be permitted for foreign taxes paid or accrued with respect to a qualifying dividend. Deduction would be unavailable for “hybrid dividends.” The dividend received deduction enacted under the TCJA may not apply to dividends from a passive foreign investment company.

U.S. Holders, other than certain U.S. Holder’s that are U.S. corporations, generally may claim the amount of Israeli withholding tax withheld either as a deduction from gross income or as a credit against U.S. federal income tax liability. However, the foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. Generally, the credit cannot exceed the proportionate share of a U.S. Holder’s U.S. federal income tax liability that such U.S. Holder’s “foreign source” taxable income bears to such U.S. Holder’s worldwide taxable income. In applying this limitation, a U.S. Holder’s various items of income and deduction must be classified, under complex rules, as either “foreign source” or “U.S. source.” In addition, this limitation is calculated separately with respect to specific categories of income. The amount of a distribution with respect to the ordinary shares that is treated as a “dividend” may be lower for U.S. federal income tax purposes than it is for Israeli income tax purposes, potentially resulting in a reduced foreign tax credit for the U.S. Holder. Each U.S. Holder should consult its own tax advisors regarding the foreign tax credit rules.

In general, the amount of a distribution paid to a U.S. Holder in a foreign currency will be the dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the U.S. Holder receives the distribution, regardless of whether the foreign currency is converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. Holder realizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in foreign currency are converted into U.S. dollars on the day they are received, a U.S. Holder generally should not be required to recognize foreign currency gain or loss in respect of the dividend.

Sale, Exchange or Other Taxable Disposition of Our Ordinary Shares

Subject to the discussion below under “-Passive Foreign Investment Company Considerations,” if you are a U.S. Holder, you generally will recognize gain or loss on the sale, exchange or other taxable disposition of our ordinary shares equal to the difference between the amount realized on such sale, exchange or other taxable disposition and your adjusted tax basis in our ordinary shares, and such gain or loss will be capital gain or loss. The adjusted tax basis in an ordinary share generally will be equal to the cost of such ordinary share. If you are a non-corporate U.S. Holder, capital gain from the sale, exchange or other taxable disposition of ordinary shares is generally eligible for a preferential rate of taxation applicable to capital gains, if your holding period determined at the time of such sale, exchange or other taxable disposition for such ordinary shares exceeds one year (i.e., such gain is long-term capital gain). The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations under the Code. Any such gain or loss that a U.S. Holder recognizes generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes.

For a cash basis taxpayer, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the settlement date of the purchase or sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such a purchase or sale. An accrual basis taxpayer, however, may elect the same treatment required of cash basis taxpayers with respect to purchases and sales of our ordinary shares that are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. For an accrual basis taxpayer who does not make such election, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the trade date of the purchase or sale. Such an accrual basis taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and the settlement date. Any foreign currency gain or loss a U.S. Holder realizes will be U.S. source ordinary income or loss.

Passive Foreign Investment Company Considerations

If we are classified as a PFIC in any taxable year, a U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation is classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of subsidiaries, either (i) at least 75% of its gross income is “passive income” or (ii) at least 50% of the average quarterly value of its total gross assets (which, assuming we are not a CFC for the year being tested, would be measured by fair market value of the assets, and for which purpose the total value of our assets may be determined in part by the market value of our ordinary shares, which is subject to change) is attributable to assets that produce “passive income” or are held for the production of passive income.

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares. If a non-U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation’s income. If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our ordinary shares, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns our ordinary shares, regardless of whether we continue to meet the tests described above.

We must determine our PFIC status annually based on tests which are factual in nature, and our status will depend on our income, assets and activities each year.

We believe that we were not a PFIC for our 2020 taxable year. However, we expect that unless and until we generate sufficient revenue from active licensing and other non-passive sources and otherwise satisfy the asset test above, we will be treated as a PFIC in future taxable years.

If we are a PFIC, and you are a U.S. Holder, then unless you make one of the elections described below, a special tax regime will apply to both (a) any “excess distribution” by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for our ordinary shares) and (b) any gain realized on the sale or other disposition of the ordinary shares. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over your holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. Holder’s regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under “Distributions.”

Certain elections may potentially be used to reduce the adverse impact of the PFIC rules on U.S. Holders (“qualifying electing fund” (“QEF”) and “mark-to-market” elections), but these elections may accelerate the recognition of taxable income and may result in the recognition of ordinary income.

The rules described above for excess distributions would not apply to a U.S. Holder if the U.S. Holder makes a timely QEF election for the first taxable year of the U.S. Holder’s holding period for ordinary shares and we comply with specified reporting requirements. A timely QEF election for a taxable year generally must be made on or before the due date (as may be extended) for filing the taxpayer’s U.S. federal income tax return for the year. A U.S. Holder who makes a QEF election generally must report on a current basis a pro rata share of our ordinary earnings and net capital gain for any taxable year in which we are a PFIC, whether or not those earnings or gains are distributed. A U.S. Holder who makes a QEF election must file a Form 8621 with its annual income tax return. We have not historically provided the information necessary for U.S. Holders to make qualified electing fund elections. However, beginning with our 2016 taxable year, for U.S. Holders who seek to make a QEF election with respect to our ordinary shares, we intend to make available an information statement that will contain the necessary information required for making a QEF election and permit such U.S. Holders access to certain information in the event of an audit by the U.S. tax authorities.

If a U.S. Holder does not make a QEF election for the first taxable year of the U.S. Holder’s holding period for ordinary shares during which we are a PFIC, the QEF election will not be treated as timely and the adverse tax regime described above would apply to dispositions of or excess distributions on the ordinary shares. In such case, a U.S. Holder may make a deemed sale election whereby the U.S. Holder would be treated as if the U.S. Holder had sold the ordinary shares in a fully taxable sale at fair market value on the first day of such taxable year in which the QEF election takes effect. Such U.S. Holder would be required to recognize any gain on the deemed sale as an excess distribution and pay any tax and interest due on the excess distribution when making the deemed sale election. The effect of such further election would be to restart the U.S. Holder’s holding period in the ordinary shares, subject to the QEF regime, and to purge the PFIC status of such ordinary shares going forward.

If a U.S. Holder makes the mark-to-market election, the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of the ordinary shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder’s tax basis in the ordinary shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ordinary shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). The mark-to-market election is available only if we are a PFIC and our ordinary shares are “regularly traded” on a “qualified exchange.” Our ordinary shares will be treated as “regularly traded” in any calendar year in which more than a de minimis quantity of the ordinary shares are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principle purposes the meeting of the trading requirement as disregarded). The NASDAQ Global Market is a qualified exchange for this purpose and, consequently, if the ordinary shares are regularly traded, the mark-to-market election will be available to a U.S. Holder.

U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are a PFIC, the general tax treatment for U.S. Holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. Holders in respect of any of our subsidiaries that also may be determined to be PFICs.

If a U.S. Holder owns ordinary shares during any year in which we are a PFIC and the U.S. Holder recognizes gain on a disposition of our ordinary shares or receives distributions with respect to our ordinary shares, the U.S. Holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the company, generally with the U.S. Holder’s federal income tax return for that year. If our company were a PFIC for a given taxable year, then you should consult your tax advisor concerning your annual filing requirements.

The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. investors are urged to consult their own tax advisers with respect to the ownership and disposition of our ordinary shares, the consequences to them of an investment in a PFIC, any elections available with respect to our ordinary shares and the IRS information reporting obligations with respect to the ownership and disposition of our ordinary shares.

Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts may be required to pay an additional 3.8% Medicare tax on all or a portion of their “net investment income,” which may include all or a portion of their dividend income and net gains from the disposition of ordinary shares. U.S. Holders will likely not be able to credit foreign taxes against the 3.8% Medicare tax. Each U.S. Holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our ordinary shares.

Backup Withholding Tax and Information Reporting Requirements

U.S. backup withholding tax and information reporting requirements may apply to certain payments to certain shareholders. Information reporting generally will apply to payments of dividends on, and to proceeds from the sale or redemption of, our ordinary shares made within the United States, or by a U.S. payor or U.S. middleman, to a holder of our ordinary shares, other than an exempt recipient (including a payee that is not a U.S. person that provides an appropriate certification and certain other persons). A payor may be required to withhold backup withholding tax from any payments of dividends on, or the proceeds from the sale or redemption of, ordinary shares within the United States, or by a U.S. payor or U.S. middleman, to a holder, other than an exempt recipient, if such holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, such backup withholding tax requirements. Any amounts withheld under the backup withholding rules should generally be allowed as a credit against the beneficial owner's U.S. federal income tax liability, if any, and any excess amounts withheld under the backup withholding rules may be refunded, provided that the required information is timely furnished to the IRS.

Foreign Asset Reporting

Certain U.S. Holders who are individuals may be required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. Holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of our ordinary shares.

Foreign Account Tax Compliance Act

The Foreign Account Tax Compliance Act ("FATCA") encourages foreign financial institutions to report information about their U.S. account holders (including holders of certain equity interests) to the IRS. Foreign financial institutions that fail to comply with the withholding and reporting requirements of FATCA and certain account holders that do not provide sufficient information under the requirements of FATCA are subject to a 30% U.S. withholding tax on certain payments they receive, including foreign passthru payments (which may include payments made by us with respect to our ordinary shares). The term "foreign passthru payment" is not currently defined in U.S. Treasury Regulations, and therefore, the future application of FATCA withholding tax on foreign pass-thru payments to holders of ordinary shares is uncertain. If a holder of ordinary shares is subject to withholding, there will be no additional amounts payable by way of compensation to the holder of such securities for the deducted amount. Holders of ordinary shares should consult their own tax advisors regarding this legislation in light of such holder's particular situation.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

You may inspect our securities filings, including this Annual Report and the exhibits and schedules thereto, without charge at the offices of the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain copies of all or any part of the Annual Report from the Public Reference Section of the SEC, 100 F Street, NE, Washington, D.C. 20549 upon the payment of the prescribed fees. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding registrants like us that file electronically with the SEC. You can also inspect the Annual Report on this website.

A copy of each document (or a translation thereof to the extent not in English) concerning our company that is referred to in this Annual Report is available for public view (subject to confidential treatment of certain agreements pursuant to applicable law) at our principal executive offices.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of foreign currency exchange rates. Approximately 33% of our expenses in 2020 were denominated in New Israeli Shekels. Changes of 5% in the US\$/NIS exchange rate will increase or decrease the operating expenses by up to 1%.

Foreign Currency Risk

Fluctuations in exchange rates, especially the NIS against the U.S. dollar, may affect our results, as some of our assets are linked to NIS, as are some of our liabilities. In addition, the fluctuation in the NIS exchange rate against the U.S. dollar may impact our results, as a portion of our operating costs are NIS denominated.

The following table presents information about the changes in the exchange rates of the NIS against the U.S. dollar at year end:

Period	%
Year ended December 31, 2020	(6.97)%
Year ended December 31, 2019	(7.79)%
Year ended December 31, 2018	8.10%

Inflation Risk

We do not believe that inflation had a material effect on our business, financial condition or results of operations in the last three fiscal years. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through hedging transactions. Our inability or failure to do so could harm our business, financial condition and results of operations.

Item 12. Description of Securities Other Than Equity Securities

Not applicable.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Use of Proceeds from Initial Public Offering

Not applicable.

Item 15. 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 the 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 the Company's 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, 2020.

This annual report does not include an attestation report of the Company's registered public accounting firm because management's report was not subject to attestation by our independent registered public accounting firm because, as a non-accelerated filer, we are exempt from this requirement.

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 year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit committee financial expert

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

Item 16B. Code of Ethics

We have adopted a Code of Business Conduct and Ethics applicable to all of our directors and employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer, or other persons performing similar functions, which is a “code of ethics” as defined in this Item 16B of Form 20-F promulgated by the SEC. The full text of the Code of Business Conduct and Ethics is posted on our website at www.vblrx.com Information contained on, or that can be accessed through, our website does not constitute a part of this Form 20-F and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code of ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC.

Item 16C. Principal Accountant 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,	
	2020	2019
	(in thousands)	
Service rendered		
Audit Fees (1)	\$ 225.0	\$ 145.0
Audit-Related Fees (2)	-	-
Tax Fees (3)	8.0	5.0
All Other Fees	-	-
Total	\$ 233.0	\$ 150.0

- (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 offering during 2019 and 2020.
- (2) Audit related services relate to reports to the IIA.
- (3) Tax fees relate to tax compliance, planning and advice.

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.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchase of Equity Securities by the Issuer and Affiliated Purchasers

In the year ended December 31, 2020, some equity securities were purchased by affiliated purchasers:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May be Purchased Under the Plans or Programs
5/11/2020	3,174,603	\$ 1.58	3,174,603	3,174,603 expires on November 11, 2021
11/24/2020-11/30/2020	83,000	\$ 1.19		
12/01/2020-12/18/2020	144,000	\$ 1.50		
Total	3,401,603		3,174,603	

Item 16F. Change in Registrant’s Certifying Accountant

None.

Item 16G. Corporate Governance

As a foreign private issuer whose shares are listed on the NASDAQ Global Market, we have the option to follow certain Israeli corporate governance practices rather than those of NASDAQ, except to the extent that such laws would be contrary to U.S. securities laws and provided that we disclose the practices we are not following and describe the home country practices we follow instead. We rely on this “foreign private issuer exemption” with respect to the following NASDAQ requirements:

- *Quorum requirement.* Under our articles of association and as permitted under the Companies Law, a quorum for any meeting of shareholders shall be the presence of at least two shareholders present in person, by proxy or by a voting instrument, who hold at least 25% of the voting power of our shares instead of 33 1 3 % of the issued share capital required under Nasdaq requirements.

Except as stated above, we comply with the rules generally applicable to U.S. domestic companies listed on NASDAQ. We may in the future elect to follow home country practices in Israel with regard to other matters, including the formation of compensation, nominating and corporate governance committees, separate executive sessions of independent directors and non-management directors and the requirement to obtain shareholder approval for certain dilutive events (such as for the establishment or amendment of certain equity-based compensation plans, issuances that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company).

Following our home country governance practices, as opposed to the requirements that would otherwise apply to a company listed on NASDAQ, may provide less protection than is accorded to investors under NASDAQ listing requirements applicable to domestic issuers. For more information, see “Item 3. Risk Factors- We are a “foreign private issuer” and intend to follow certain home country corporate governance practices, and our shareholders may not have the same protections afforded to shareholders of companies that are subject to all NASDAQ corporate governance requirements. Additionally, we cannot be certain if the reduced disclosure requirements applicable to our status as a foreign private issuer, will make our ordinary shares less attractive to investors.” We will also be required to comply with Israeli corporate governance requirements under the Companies Law applicable to Israeli public companies such as us whose shares are also listed for trade on an exchange outside Israel.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

Financial Statements are set forth under Item 18.

Item 18. Financial Statements

Our Financial Statements beginning on pages F-1 through F-8, as set forth in the following index, are incorporated herein by reference. These Financial Statements are filed as part of this Annual Report.

	Page
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	F-2
STATEMENTS OF FINANCIAL POSITION	F-3
STATEMENTS OF NET LOSS AND COMPREHENSIVE LOSS	F-4
STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY	F-5
STATEMENTS OF CASH FLOWS	F-6
NOTES TO THE FINANCIAL STATEMENTS	F-7



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 statements of financial position of Vascular Biogenics Ltd. (the "Company") as of December 31, 2020 and 2019, and the related statements of net loss and comprehensive loss, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2020, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2(p) to the financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

/s/ **Kesselman & Kesselman**

Certified Public Accountants (Isr.)

A member of PricewaterhouseCoopers International Limited

Tel Aviv, Israel

March 25, 2021

We have served as the Company's auditor since 2001.

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VASCULAR BIOGENICS LTD.
STATEMENTS OF FINANCIAL POSITION

	December 31	
	2020	2019
	U.S. dollars in thousands	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 13,184	\$ 9,436
Restricted bank deposits	151	-
Short-term bank deposits	17,110	27,100
Trade receivables	129	-
Other current assets	1,419	1,241
Total current assets	31,993	37,777
Non-current assets:		
Restricted bank deposits	\$ 362	506
Long-term prepaid expenses	241	300
Funds in respect of employee rights upon retirement	354	318
Property, plant and equipment, net	6,632	7,775
Operating lease right-of-use assets	2,124	2,329
Total non-current assets	9,713	11,228
Total assets	\$ 41,706	\$ 49,005
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable:		
Trade	\$ 1,960	\$ 3,330
Other	4,275	4,176
Deferred revenue	725	386
Current maturity of operating leases	393	385
Current maturity of finance lease liability	106	389
Total current liabilities	7,459	\$ 8,666
Non-current liabilities:		
Liability for employee rights upon retirement	474	426
Deferred revenue	704	1,723
Operating lease liability	2,029	2,068
Finance lease liability	-	99
Other non-current liability	123	-
Total non-current liabilities	3,330	4,316
Total liabilities	\$ 10,789	\$ 12,982
Commitments (Note 8)		
Shareholders' equity:		
Ordinary shares, NIS 0.01 par value; Authorized as of December 31, 2020 and 2019, 150,000,000 and 70,000,000 shares, respectively; issued and outstanding as of December 31, 2020 and 2019, 48,187,463 and 35,882,928 shares, respectively	108	73
Additional paid in capital	252,561	235,974
Warrants	10,401	7,904
Accumulated deficit	(232,153)	(207,928)
Total equity	30,917	36,023
Total liabilities and equity	\$ 41,706	\$ 49,005

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

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

	Year ended December 31		
	2020	2019	2018
	U.S. dollars in thousands		
Revenues	\$ 922	\$ 562	\$ 585
Cost of revenues	(394)	(222)	(255)
Gross profit	528	340	330
Research and development expenses, net	19,656	14,714	15,178
Marketing expenses	-	-	397
General and administrative expenses	5,355	5,708	6,000
Operating loss	24,483	20,082	21,245
Financial income	(363)	(870)	(908)
Interest expenses	105	184	159
Financial (income), net	(258)	(686)	(749)
Net loss and comprehensive loss	\$ 24,225	\$ 19,396	\$ 20,496
	U.S. dollars		
Loss per ordinary share			
Basic and diluted	\$ 0.55	\$ 0.54	\$ 0.62
	Number of shares		
Weighted average ordinary shares outstanding			
Basic and diluted	43,668,155	35,881,256	32,969,094

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

VASCULAR BIOGENICS LTD.
STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

	Number of ordinary shares	Ordinary shares	Additional paid in capital	Warrants	Accumulated deficit	Total equity
	U.S. dollars in thousands					
Balance at January 1, 2018	29,879,323	\$ 57	\$ 221,055	\$ 2,960	\$ (168,036)	\$ 56,036
Changes during the year ended December 31, 2018:						
Net loss	-	-	-	-	(20,496)	(20,496)
Exercise of options by employees	97,043	*	34	-	-	34
Issuance of ordinary shares and warrants, net of issuance costs in an amount of \$1,775 thousand	5,904,762	16	8,765	4,944	-	13,725
Share-based compensation	-	-	3,867	-	-	3,867
Balance at December 31, 2018	<u>35,881,128</u>	<u>73</u>	<u>233,721</u>	<u>7,904</u>	<u>(188,532)</u>	<u>53,166</u>
Changes during the year ended December 31, 2019:						
Net loss	-	-	-	-	(19,396)	(19,396)
Issuance of ordinary shares	1,800	*	2	-	-	2
Share-based compensation	-	-	2,251	-	-	2,251
Balance at December 31, 2019	<u>35,882,928</u>	<u>73</u>	<u>235,974</u>	<u>7,904</u>	<u>(207,928)</u>	<u>36,023</u>
Changes during the year ended December 31, 2020:						
Net loss	-	-	-	-	(24,225)	(24,225)
Issuance of ordinary shares and warrants, net of issuance costs of \$1,674 thousands	12,304,535	35	13,110	4,313	-	17,458
Expired warrants	-	-	1,816	(1,816)	-	-
Share-based compensation	-	-	1,661	-	-	1,661
Balance at December 31, 2020	<u><u>48,187,463</u></u>	<u><u>\$ 108</u></u>	<u><u>\$ 252,561</u></u>	<u><u>\$ 10,401</u></u>	<u><u>\$ (232,153)</u></u>	<u><u>\$ 30,917</u></u>

* Amount less than \$1 thousand

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

	Year ended December 31,		
	2020	2019	2018
U.S. dollars in thousands			
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (24,225)	\$ (19,396)	\$ (20,496)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,194	\$ 1,219	1,156
Interest income	48	61	(57)
Net changes in operating leases	174	241	(60)
Loss from sale of property and equipment	-	-	47
Interest expenses on leases	9	54	-
Exchange losses (gains) on cash and cash equivalents	(175)	(143)	71
Changes in accrued liability for employee rights upon retirement	12	6	13
Share-based compensation	1,661	2,251	3,867
Changes in operating assets and liabilities:			
Decrease (increase) in other current assets and long-term prepaid expenses	(119)	(381)	2,502
Decrease (increase) in trade receivables	(129)	-	55
Increase (decrease) in accounts payable:			
Trade	(1,370)	2,136	(1,691)
Other (including other non-current liability)	222	1,307	(502)
Decrease in deferred revenue	(680)	(444)	(585)
Net cash used in operating activities	<u>\$ (23,378)</u>	<u>\$ (13,089)</u>	<u>\$ (15,680)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(51)	(73)	(2,229)
Proceeds from sale of property and equipment	-	-	4
Investment in short-term bank deposits	(41,085)	(63,027)	(21,000)
Maturity of short-term bank deposits	51,027	57,000	47,958
Net cash provided by (used in) investing activities	<u>\$ 9,891</u>	<u>\$ (6,100)</u>	<u>\$ 24,733</u>
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of options by employees	-	-	34
Proceeds from issuance of ordinary shares and warrants, net of issuance costs	17,458	2	13,725
Finance lease payments	(391)	(361)	(88)
Net cash provided by (used in) financing activities	<u>\$ 17,067</u>	<u>\$ (359)</u>	<u>\$ 13,671</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	3,580	(19,548)	22,724
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF YEAR	9,942	29,347	6,694
EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	175	143	(71)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF YEAR	<u><u>\$ 13,697</u></u>	<u><u>\$ 9,942</u></u>	<u><u>\$ 29,347</u></u>
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:			
Non cash activity - Purchase of property and equipment in payables	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 796</u>
Right of use assets obtained in exchange for new operating lease liabilities	<u>\$ 230</u>	<u>\$ 28</u>	<u>\$ -</u>
RECONCILIATION OF CASH, CASH EQUIVALENTS, AND RESTRICTED CASH REPORTED IN THE STATEMENT OF FINANCIAL POSITION			
Cash and cash equivalents	13,184	9,436	29,347
Restricted bank deposits	151	-	-
Restricted bank deposits included in non-current assets	362	506	-
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	<u>13,697</u>	<u>9,942</u>	<u>29,347</u>
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS			
Interest received	<u>\$ 416</u>	<u>\$ 927</u>	<u>\$ 849</u>
Interest paid	<u>\$ (9)</u>	<u>\$ (20)</u>	<u>\$ (22)</u>

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES:

a. General

Vascular Biogenics Ltd. (the “Company” or VBL) was incorporated on January 27, 2000. The Company is a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of first-in-class treatments for cancer and immune/inflammatory indications. VB-111 (ofranergene obadenovec), a Phase 3 drug candidate, is the lead product candidate in the Company’s cancer program.

VB-600 series are preclinical stage antibodies targeting MOSPD2 for inflammatory and oncology indications, which are being advanced towards IND VB-601 is the lead mAb candidate for various inflammatory indications and VB-611 is the lead bi-specific mAb for various solid tumors.

VB-201, a Phase 2-ready drug candidate, is the Company’s lead Lecinioxid-based product candidate for chronic immune-related indications.

The Company is engaged in an exclusive license agreement with NanoCarrier Co., Ltd. (hereinafter - “The License Agreement”) for the development, commercialization, and supply of ofranergene obadenovec (“VB-111”) in Japan for all indications, see notes 1(m) and 7.

In March 2019, the Company entered into an exclusive option license agreement with an animal health company for the development of VB-201 for veterinary use, see note 7.

Since inception, the Company 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, 2020, the Company had an accumulated deficit of \$232.2 million. The Company’s 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, and its expenditures on other research and development activities.

As of December 31, 2020, the Company had cash, cash equivalents, short-term bank deposits and restricted cash of \$30.8 million. The Company may seek to raise more capital to pursue additional activities. The Company may seek these funds through a combination of private and public equity offerings, government grants, strategic collaborations and licensing arrangements. Additional financing may not be available when the Company needs it or may not be available on terms that are favorable to the Company.

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”).

Prior to 2020, the Company prepared its financial statements in accordance with International Financial Reporting Standards (“IFRS”), as issued by the International Accounting Standards Board (“IASB”), as permitted in the United States (“U.S.”) based on the Company’s status as a foreign private issuer as defined by the U.S. Securities and Exchange Commission (the “SEC”). During 2020, the Company decided to adopt the US GAAP to better accommodate with the expectation of the US based investors and capital markets. There were no material IFRS to US GAAP adjustments made upon adoption of US GAAP.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):**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 currency of the Company 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 as cash equivalents all short-term, highly liquid investments, which include 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 by operating and financial lease contractual agreements recorded in current assets and non-current assets, respectively, on the balance sheet.

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 charged to the statement of operations 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:

	%
Laboratory equipment	9-15
Computers	25-33
Office furniture and equipment	7

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

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. 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, 2020, no impairment has been recognized.

h. Deferred income tax

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

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.

i. 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.

j. 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 a liability in its balance sheet.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

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. The Company recognizes a liability and an 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.

Until December 31, 2018, when options and RSUs were granted as consideration for services provided by consultants and other non-employees, the grant was accounted for based on the fair value of the consideration received or the fair value of the awards issued, whichever was more reliably measurable. The fair value of the awards granted was measured on a final basis at the end of the related service period and recognized over the related service period using the straight-line method.

After the adoption of ASU 2018-07 on January 1, 2019, fair value of all grants of options and RSUs is determined by reference to their fair value at date of grant.

Service conditions and 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

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, 2020, no contingent liabilities have been recognized.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

m. Revenue from contracts with customers:

General

The Company recognized revenues from the 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.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

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 was reasonable assurance that the Company will comply with the conditions attached to the grant and there was reasonable assurance the grant will be received.

The grant is deducted from the research and development expenses as the applicable costs are incurred. Research and development expenses, net for the years ended December 31, 2020, 2019 and 2018, include participation in research and development expenses in the amount of approximately \$1.4 million, \$2.7 million and \$2 million, respectively.

p. Leases

Until December 31, 2018

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases are charged to the statements of operations on a straight-line basis over the period of the lease.

Leases of property, plant and equipment where the Company, as lessee, has substantially all the risks and rewards of ownership are classified as finance leases. Finance leases are capitalized at the lease's inception at the fair value of the leased property or, if lower, the present value of the minimum lease payments. The corresponding rental obligations, net of finance charges, are included in short-term lease liability and long-term lease liability. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to the profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The property, plant and equipment acquired under finance leases is depreciated over the asset's useful life or over the shorter of the asset's useful life and the lease term if there is no reasonable certainty that the Company will obtain ownership at the end of the lease term.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

After January 1, 2019

In February 2016, the FASB issued a new standard, ASC 842, related to leases to increase transparency and comparability among organizations by requiring the recognition of ROU assets and lease liabilities on the balance sheet. Most prominent among the changes in the standard is the recognition of ROU assets and lease liabilities by lessees for those leases classified as operating leases. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The Company adopted the standard as of January 1, 2019, using the simplified transition approach, therefore did not restate comparative amounts for the year prior to first adoption. The new standard resulted in an increase of \$2.7 million in operating lease ROU assets and corresponding liabilities on the Company's balance sheet and did not have a material impact on the Company's statement of income or statement of cash flows.

Under ASC 842, the Company determines if an arrangement is a lease at inception. Upon initial recognition, the Company recognizes a liability at the present value of the lease payments to be made over the lease term, and concurrently recognizes a ROU asset at the same amount of the liability, adjusted for any prepaid or accrued lease payments, plus initial direct costs incurred in respect of the lease. Since the interest rate implicit in the lease is not readily determinable, the incremental borrowing rate of the Company is used. The subsequent measurement depends on whether the lease is classified as finance lease or an operating lease.

For operating leases, after lease commencement, the Company measures the lease liability at the present value of the remaining lease payments using the discount rate determined at lease commencement. The Company subsequently measures the ROU asset at the present value of the remaining lease payments, adjusted for the remaining balance of any lease incentives received, any cumulative prepaid or accrued rent if the lease payments are uneven throughout the lease term and any unamortized initial direct costs. Further, the Company will recognize lease expense on a straight-line basis over the lease term.

For finance leases, after lease commencement, the Company measures the lease liability by increasing the carrying amount to reflect interest on the lease liability and reducing the carrying amount to reflect the lease payments made during the period. The Company measures the ROU assets at cost less any accumulated amortization and any accumulated impairment losses. The Company amortizes the ROU asset on a straight-line basis over approximately 7 years, unless another systematic basis better represents the pattern in which the Company expects to consume the ROU asset's future economic benefits.

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 operates in one operating segment.

r. Loss per Ordinary Share

Basic loss per share is calculated by dividing the net loss by the weighted average number of Ordinary Shares issued and outstanding during the year. Diluted loss per share is based upon the weighted average number of ordinary shares and of ordinary shares equivalents outstanding when dilutive. Ordinary share equivalents include outstanding stock options and warrants which are included under the treasury stock method when dilutive. The dilutive potential shares were not taken into account in computing loss per share in 2020, 2019 and 2018 as their effect would not have been dilutive.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued):

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.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

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, 2020, and 2019, the fair value of financial instruments (cash and cash equivalents, short term bank deposits, other current assets and accounts payable) are approximate to their carrying value.

NOTE 3 – SHORT-TERM BANK DEPOSITS

The bank deposits in 2020 of \$17,110 thousand are for terms of three months to one year and carry interest at annual rates of 0.01%-0.75%. The bank deposits in 2019 of \$27,100 thousand are for terms of three months to one year and carry interest at annual rates of 1.87%-2.15%.

NOTE 4 – PROPERTY AND EQUIPMENT

	December 31	
	2020	2019
	(in thousands)	
Cost:		
Laboratory equipment*	\$ 4,705	\$ 4,667
Computers	304	291
Office furniture and equipment	198	198
Leasehold improvements	\$ 6,653	6,653
	<u>\$ 11,860</u>	<u>\$ 11,809</u>
Less:		
Accumulated depreciation	\$ 5,228	\$ 4,034
Property and Equipment, net	<u>\$ 6,632</u>	<u>\$ 7,775</u>

*Laboratory equipment category includes the finance lease (see also Note 5) with cost of \$1.1 million as of December 31, 2020 and 2019. The related accumulated depreciation for the finance lease as of December 31, 2020 and 2019 is \$0.5 million and \$0.3 million, respectively.

Depreciation expense totaled \$1,194 thousand, \$1,219 thousand and \$1,156 thousand for the years ended December 31, 2020, December 31, 2019 and December 31, 2018, respectively.

During the years ended December 31, 2020 and December 31, 2019, the Company did not dispose of any fixed assets.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 5 – LEASES

Operating lease

- 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. The site houses the Company's local biological drugs manufacturing facility, headquarters, discovery research and clinical development. A restricted deposit for \$362 thousand has been set aside for the Modi'in facility lease and is included in non-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.

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. The restricted deposits for \$151 thousand have been set aside for the water purification system and is included in current assets on the balance sheet.

Prior to the implementation of ASC 842, leases were accounted for in accordance with ASC 840.

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

	Year ended December 31,	
	2020	2019
	(in thousands)	
Lease cost		
Finance lease cost:		
Amortization of right-of-use assets	\$ 168	\$ 168
Interest on lease liabilities	9	20
Operating lease cost	535	554
Other information		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	\$ 391	\$ 361
Operating cash flows from operating leases	530	506
Financing cash flows from finance leases	9	20
Right-of-use assets obtained in exchange for new operating lease liabilities	\$ 230	\$ 200
Weighted-average remaining lease term - finance leases	0.25	1.25
Weighted-average remaining lease term - operating leases	5.92	7.01

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 5 – LEASES (continued):

	Year ended December 31,	
	2020	2019
Weighted-average discount rate - finance leases	3.0%	3.0%
Weighted-average discount rate - operating leases	4.1%	4.2%

Future minimum lease payments under non-cancellable leases as of December 31, 2020 were as follows:

Year ending December 31,	Operating Leases		Finance Leases	
	(Dollars in thousands)			
2021	\$	487	\$	106
2022		466		-
2023		415		-
2024		406		-
2025		420		-
Thereafter		561		-
Total future minimum lease payments		2,755		106
Less imputed interest		(333)		-
Total	\$	2,422	\$	106

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

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 by 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 does 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 fund under Section 14 for such employees is recorded on the Company's balance sheet as the Company's relieved of its obligation upon contribution.

For certain Israeli employees, the Company accrued 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 of employees' rights upon retirement.

During the five-year period following December 31, 2020, the Company expects to pay future benefits to two employees upon each such employee's normal retirement age. The Company anticipates that the benefits payable will be approximately \$75 thousands.

The amounts of severance pay expenses were approximately \$225 thousand, \$221 thousand and \$191 thousand for each of the years ended December 31, 2020, 2019 and 2018, respectively, of which approximately \$225 thousand, \$221 thousand and \$191 thousand in the years ended December 31, 2020, 2019 and 2018, respectively, were in respect of the Contribution Plans. Gain on amounts funded in respect of employee rights upon retirement for the years ended December 31, 2020, 2019 and 2018 was immaterial.

The Company expects to contribute approximately \$225 thousand in the year ending December 31, 2020 to insurance companies in connection with its severance liabilities for its operations for that year, approximately \$225 thousand 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.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

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 VB-111 in Japan. VBL retains rights to VB-111 in the rest of the world (“The License Agreement”). Under terms of the agreement, VBL has granted NanoCarrier an exclusive license to develop and commercialize VB-111 in Japan for all indications. VBL will supply NanoCarrier with VB-111, 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 additional payments only if certain development or commercial milestones are achieved. VBL will also receive tiered royalties on net sales. In addition, in case NanoCarrier will enter into a sublicense agreement, the Company will be entitled to receive royalties from sublicense income received by NanoCarrier.

In March 2019, the Company entered into exclusive option license agreement (hereafter- Agreement) with an animal health company, for the development of VB-201 for veterinary use. Under the Agreement, the Company granted a right to use intellectual property and transfer materials. In addition, the Company granted an option to obtain an exclusive worldwide, royalty-bearing, transferable license under the Company’s intellectual property and materials to research, develop and sell the product worldwide.

As part of the Agreement, the Company received an immaterial non-refundable and non-creditable upfront payment recognized as revenues during 2019. In addition, the Company is entitled to receive an immaterial amount upon the achievement of a milestone event.

The performance obligation relating to the Company’s participation and consulting assistance services during the development period is recognized over the service period. During 2020, 2019 and 2018 the Company recognized revenue in an amount of \$0.9 million, \$0.6 million and \$0.6 million, respectively related to the Company’s participation and consulting assistance services of VB-111 in Japan for all indications and from the option to license agreement for the development of VB-201 for animal healthcare worldwide. Out of the consideration received in the License Agreement as of December 31, 2020, the Company has deferred revenue in the amount of \$1.4 million in 2020 (\$0.7 million is classified within current liabilities, and \$0.7 million is classified within non-current liabilities, which will be recognized until 2022).

All revenues recognized in 2018 were related to the Company’s participation and consulting assistance services. Revenues recognized in 2020 and 2019 were related to the Company’s participation and consulting assistance services from the License Agreement and from the option to license agreement for the development of VB-201 for animal healthcare worldwide. The major part of revenues recognized in 2020 were included in the opening balance of the deferred revenue in the statements of financial position.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

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 VB-111 and other drug candidates for cancer for consideration including the following potential future payments:
- an annual license fee of €100 thousand (\$123 thousand) that is linked to Consumer Price Index (in 2020, 2019 and 2018 the Company paid \$132 thousand, \$138 thousand and \$144 thousand, respectively), 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 VB-111 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 €400 thousand (\$492 thousand) 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%-2.0% on net sales.

There are no limits or caps on the amount of potential royalties. Pursuant to the agreement, the Company has the right to terminate the agreement by giving Janssen three months’ written notice.

- 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 operations under research and development costs.

Until December 31, 2020, the Company paid Tel Hashomer a total amount of \$747 thousand in consideration for the payments received for granting the licenses or similar rights to this intellectual property.

- 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. 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 so funded up to 100% of the amount of the grant received by the Company (dollar linked) with the addition of an annual interest based on Libor. As of December 31, 2020, the total additional royalty amount that may be payable by the Company, before the additional Libor interest, is approximately \$28.8 million (\$36.0 million including interest). To date, the Company has paid the IIA in relation to its licenses agreement royalties of approximately \$0.5 million.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 8 – COMMITMENTS (continued):

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. The Ordinary Shares confer upon their holders the following rights: (i) the right to vote in any general meeting of the Company; (ii) the right to receive dividends; and (iii) the right to receive upon liquidation of the Company a sum equal to the nominal value of the share, and if a surplus remains, to receive such surplus.
- b. On June 25, 2018, the Company entered into securities purchase agreements related to the registered direct offering of an aggregate of 5,904,762 ordinary shares, NIS 0.01 nominal value, at a purchase price of \$2.50 per share and accompanying short-term warrants to purchase up to 2,952,381 ordinary shares and long-term warrants to purchase up to 2,952,381 ordinary shares at an additional purchase price per warrant combination of \$0.125. The combined offering price of each ordinary share and accompanying warrants is \$2.625 per unit for aggregate gross proceeds of approximately \$15.5 million. The ordinary shares and the warrants are immediately separable and were issued separately. The net proceeds from this offering, which closed on June 27, 2018 were \$13.7 million after deducting the underwriting discounts and commissions and offering costs payable by the Company. The short-term and long-term warrants are exercisable immediately after issuance and will expire on January 6, 2020 and June 26, 2022, respectively at an exercise price of \$2.51 and \$3.00 per one ordinary share, respectively. The fair value of the separable warrants on the date of purchase was computed using the Black-Scholes model. The underlying data used for computing the fair value of the short-term and long-term warrants are mainly as follows: ordinary share price based on the share's price at the stock market on June 25, 2018: \$2.40; expected volatility based on Company historical trade: 88.0% and 109%; risk-free interest rate: 2.279% and 2.715% (the risk-free interest rate is determined based on rates of return on maturity of unlinked treasury bonds with time to maturity that equals the average life of the warrants); expected dividend: zero; and expected life to exercise of 1.5 years and 4.0 years, respectively. The consideration was allocated between ordinary shares and warrants based on the ratio of the warrants' fair value and the ordinary share price.

On January 6, 2020, 2,952,381 short-term warrants related to June 25, 2018 registered direct offering were expired.

- c. On May 17, 2019, the Company entered into an Equity Distribution Agreement with Oppenheimer & Co. Inc., or Oppenheimer to offer and sell from time to time its ordinary shares, NIS 0.01 par value, having an aggregate offering price of up to \$15,000,000 through Oppenheimer acting as its agent and/or principal. For the year-ended December 31, 2020, the Company sold an aggregate of 812,470 ordinary shares under its at-the-market equity facility. The total consideration amounted to \$1,034 thousand, net of issuance costs.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 9 – SHARE CAPITAL (continued):

- d. On May 7, 2020 and May 11, 2020, the Company entered into securities purchase agreements with several institutional investors and existing shareholders to purchase 11,492,065 of the Company's ordinary shares at a purchase price of \$1.575 per share in a registered direct offering. In a concurrent private placement, the Company issued to investors and existing shareholders in the offering unregistered warrants to purchase up to 11,492,065 ordinary shares. Each warrant is exercisable immediately upon issuance at an exercise price of \$1.45 per share and will remain exercisable for 18 months following issuance date. The offering raised a total of \$18.1 million, with net proceeds of \$16.4 million, after deducting fees and expenses. The closing of the sale of the ordinary shares and warrants occurred on May 11, 2020 and May 13, 2020.

The fair value of the warrants is computed using the Black-Scholes option-pricing model. The underlying data used for computing the fair value of the warrants are mainly as follows: ordinary share price based on the current price of an ordinary share: \$1.27-\$1.63; expected volatility based on Company historical trade: 74%-76%; risk-free interest rate: 0.155%-0.165%; expected dividend: zero; and expected life to exercise of 1.5 years. The consideration was allocated between ordinary shares and warrants based on the ratio of the warrants' fair value and the ordinary share price.

As of December 31, 2020, none of the warrants were exercised.

- e. On July 29, 2020, the general meeting of the shareholders of the Company approved the increase of the authorized share capital of the Company by 80,000,000 ordinary shares to 150,000,000 ordinary shares, par value NIS 0.01 per share.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 9 – SHARE CAPITAL (continued):**f. Share based compensation plans**

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 is exercisable to acquire one Ordinary Share. 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.

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

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.

Options granted in 2018, 2019 and 2020:

Date of grant	Number of options granted according to option plan of the company Total	Exercise price per Ordinary Share (\$)	The fair value of options on date of grant (in thousands)
January 2018	128,000	\$ 6.9	\$ 838
June 2018	50,000	\$ 2.22	\$ 119
September 2018	30,000	\$ 1.78	\$ 46
December 2018	1,305,000	\$ 1.22	\$ 1,300
December 2019	1,346,000	\$ 1.22	\$ 1,411
November 24, 2020	125,000	\$ 1.17	\$ 135
December 8, 2020	1,343,000	\$ 1.22	\$ 1,753

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 9 – SHARE CAPITAL (continued):

All of the options granted in 2018, 2019, 2020 will vest by 4 years with 25% on the first-year anniversary; the remaining 75% at 1/12 of the options at the end of each quarter over the course of the last 3 years.

The fair value of the options on the date of grant was computed using the Black-Scholes model. Fair value of the options was estimated using the expected volatility. The risk-free interest rate was determined based on rates of return on maturity of unlinked treasury bonds with time to maturity that equals the average life of the options.

The fair value of the Company’s stock options and RSUs granted for the years ended December 31, 2020, 2019 and 2018 was estimated using the following assumptions:

	2020	2019	2018
Value of one ordinary share	\$1.21 -\$1.45	\$1.15	\$1.09- \$7.20
Expected stock price volatility	94 %	100%	97%-100%
Expected term (in years)	11	11	11
Risk free interest rate	0.88%-0.91%	1.91%	2.46%-2.93%
Dividend yield	-	-	-

g. Changes in the number of options and RSUs and weighted average exercise prices are as follows:

	Year ended December 31					
	2020		2019		2018	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of year	6,373,331	\$ 2.91	5,056,914	\$ 3.36	4,036,095	\$ 3.88
Granted	1,468,000	1.22	1,346,000	1.22	1,513,000	1.74
Exercised	-	-	-	-	(97,042)	0.33
Forfeited and expired	(271,705)	4.35	(29,583)	3.30	(395,140)	3.31
Outstanding at end of year (1)	7,569,626	\$ 2.53	6,373,331	\$ 2.91	5,056,914	\$ 3.36
Exercisable at end of year	4,149,359	\$ 3.43	3,294,647	\$ 3.73	2,478,796	\$ 3.70

(1) Out of which number of RSUs 102,334, 102,334 and 114,668 for the years ended December 31, 2020, 2019 and 2018, respectively

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 9 – SHARE CAPITAL (continued):

h. The following is information about exercise price and remaining contractual life of outstanding options and RSUs at year-end:

December 31, 2020			December 31, 2019			December 31, 2018		
Number of options outstanding at end of year	Exercise Price	Weighted average of remaining contractual life	Number of options outstanding at end of year	Exercise price	Weighted average of remaining contractual life	Number of options outstanding at end of year	Exercise Price	Weighted average of remaining contractual life
509,176	\$ 0.002	10.14	509,176	\$ 0.002	10.88	521,509	\$ 0.002	11.34
125,000	\$ 1.17	19.91	-	-	-	-	-	-
72,990	\$ 1.21	3.72	72,990	\$ 1.21	4.72	72,990	\$ 1.21	5.72
4,491,494	\$ 1.22-2.47	16.61	3,244,969	\$ 1.22-2.47	30.38	1,898,969	\$ 1.22-2.47	15.54
538,871	\$ 3.30-3.48	11.92	559,871	\$ 3.30-3.48	12.96	559,871	\$ 3.30-3.48	13.96
30,000	\$ 6.03	14.12	60,000	\$ 6.03	15.13	60,000	\$ 6.03	16.13
106,625	\$ 6.90	17.02	116,000	\$ 6.90	18.02	116,000	\$ 6.9	19.2
342,470	\$ 7.52	14.88	372,470	\$ 7.52	15.88	372,470	\$ 7.52	16.88
1,353,000	\$ 5.08-5.99	16.36	1,437,855	\$ 5.08-5.99	17.36	1,455,105	\$ 5.08-5.99	18.38
7,569,626			6,373,331			5,056,914		

The aggregate intrinsic value for the options outstanding as of December 31, 2020, 2019 and 2018 was \$3.7 million, \$0.6 million and, \$0.5 million, respectively.

i. Expenses for share based compensation recognized in statements of operations were as follows:

	Year ended December 31		
	2020	2019	2018
	U.S. dollars in thousands		
Research and development expenses	\$ 834	\$ 1,236	\$ 2,255
Administrative and general expenses	827	1,015	1,541
Marketing expenses	-	-	71
	<u>\$ 1,661</u>	<u>\$ 2,251</u>	<u>\$ 3,867</u>

The remaining unrecognized compensation expenses as of December 31, 2020 are \$2,680 thousand; The unrecognized compensation cost is expected to be recognized over a weighted average period of 1.1 years.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

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, 2020, the period of benefits has not yet commenced.

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.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 10 – TAXES ON INCOME (continued):

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 (inter alia, if the amount of foreign investors in the distributing company exceeds 90%). 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%.

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, 2020, 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.

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 10 – TAXES ON INCOME (continued):

d. Losses for tax purposes carried forward to future years

The balance of carry forward losses as of December 31, 2020 is \$198.1 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 2015.

f. Deferred Taxes

The following table presents summary of information concerning the Company's deferred taxes as of the periods ending December 31, 2020 and December 31, 2019.

	December 31	
	2020	2019
	U.S. dollars in thousands	
In respect of:		
Net operating loss carry forwards	45,553	41,605
Research and development expenses	3,244	1,954
Other timing differences	375	211
Less – valuation allowance	(49,172)	(43,770)
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:

	December 31,	
	2020	2019
	(U.S. dollars in thousands)	
Balance at the beginning of year	\$ 43,770	\$ 40,589
Additions during the year	5,402	3,181
Balance at end of year	\$ 49,172	\$ 43,770

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).

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 11 – SUPPLEMENTARY FINANCIAL INFORMATION:

	December 31	
	2020	2019
	U.S. dollars in thousands	
a. Other current assets:		
Institutions - VAT	\$ 187	\$ 205
Prepaid expenses	1,215	602
Government grants receivable	6	424
Other	11	10
	\$ 1,419	\$ 1,241
b. Accounts payable-other:		
Accrued expenses	\$ 3,632	\$ 3,650
Employee-related accrued expenses	337	309
Provision for vacation	306	217
	\$ 4,275	\$ 4,176

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, 2020, 2019 and 2018 since their effect was anti-dilutive. The total number of options, RSU's and warrants excluded from the calculations of diluted loss per share were – 23,264,072, 13,528,092 and 12,211,676 for the years ended December 31, 2020, 2019 and 2018, respectively.

	Year ended December 31		
	2020	2019	2018
	U.S. dollars in thousands, except per share data		
Basic and diluted:			
Loss attributable to equity holders of the Company	\$ 24,225	\$ 19,396	\$ 20,496
Weighted average number of ordinary shares in issue	43,668,155	35,881,256	32,969,094
Loss per ordinary share	\$ 0.55	\$ 0.54	\$ 0.62

VASCULAR BIOGENICS LTD.
NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 13 – SUBSEQUENT EVENT:

- a. On January 14, 2021, the Company entered into an ordinary share purchase agreement (Agreement) of up to \$20 million of the Company's ordinary shares, par value NIS 0.01 per share, with Aspire Capital Fund, LLC. The ordinary shares may be sold from time to time based on the Company's notice to Aspire Capital over the 30-month term of the purchase Agreement.
- b. During January and February 2021 the Company issued 6,947,272 ordinary shares out of which (a) 4,861,906 shares issued from exercise of warrants; (b) 1,285,366 shares from the At-The-Market (ATM); and (c) sale of 800,000 shares to Aspire Capital Fund, LLC under the Agreement. The accumulated gross proceeds from the sale of the above shares is approximately \$12,345 thousand.

Regarding the ATM sales the Company failed to file a prospectus supplement specifying details regarding such sales. This may have constituted a violation of Section 5 of the Securities Act and may give rise to liability under Section 12 of the Securities Act (which generally provides a rescission remedy for offers and sales of securities in violation of Section 5) as well as potential liability under the anti-fraud provisions of federal and state securities laws and state rescission laws.

In such event, anyone who acquired such ordinary shares would have a right to rescind the purchase. If all the shareholders who acquired ordinary shares demanded rescission, the maximum that the Company would be obligated to repay would be approximately \$3,500 thousand, plus interest. Out of the \$3,500 thousand, there was an identified buyer of approximately \$1,900. That buyer has agreed to waive his rescission right and signed a respective waiver. The Securities Act generally requires that any claim brought for a violation of Section 5 of the Securities Act be brought within one year of the violation. Additionally, if it is determined that such sales did in fact violate the Securities Act, the Company may become subject to fines and penalties imposed by the SEC and state securities agencies. Management is evaluating the impact of this matter on the Company including the penalty to be recorded as such transactions occurred in 2021.

Item 19. Exhibits

Exhibit No.	Description
1.1	Articles of Association of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.2 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on September 30, 2014).
1.2	Memorandum of Association of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.4 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on September 30, 2014).
2.1	Form of Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.2 of Registration Statement on Form F-1 filed with the Securities and Exchange Commission on July 29, 2014).
2.2	Warrant to purchase ordinary shares, dated April 1, 2001, issued to Dror Harats, as amended (incorporated by reference to Exhibit 4.4 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on June 6, 2014).
2.3	Warrant to purchase ordinary shares, dated May 14, 2001, issued to Dror Harats, as amended (incorporated by reference to Exhibit 4.5 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on June 6, 2014).
2.4	Warrant to purchase ordinary shares, dated December 28, 2001, issued to Dror Harats, as amended (incorporated by reference to Exhibit 4.6 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on June 6, 2014).
2.5	Form of Warrant to purchase ordinary shares, (incorporated by reference to Exhibit 4.2 of the Current Report on Form 6-K filed with the Securities and Exchange Commission on November 5, 2015).
2.6	Form of Series B Warrant to purchase ordinary shares (incorporated by reference to Exhibit 4.1 of the Current Report on Form 6-K filed with the Securities and Exchange Commission on June 27, 2018).
2.7*	Description of Securities
4.1	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).
4.2	Form of Release and Indemnification Agreement to be entered into between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.3 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on June 25, 2014).
4.3†	Commercial Gene Therapy License Agreement, dated April 15, 2011, between the Registrant and Crucell Holland B.V. (incorporated by reference to Exhibit 10.3 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on July 18, 2014).
4.4†	Agreement, dated February 3, 2013, between the Registrant and Tel Hashomer-Medical Research, Infrastructure and Services Ltd. (incorporated by reference to Exhibit 10.4 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on July 18, 2014).
4.5†	Manufacturing Services Agreement, dated January 5, 2012, between the Registrant and Lonza Houston, Inc. (incorporated by reference to Exhibit 10.5 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on July 18, 2014).

Exhibit No.	Description
4.6†	Material Transfer and Confidentiality Agreement, effective as of September 19, 2005, among the Registrant, Crucell Holland B.V. and BioReliance Ltd. (incorporated by reference to Exhibit 10.9 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on July 18, 2014).
4.7†	Material Transfer and Confidentiality Agreement, effective February 6, 2012 between the Registrant, Crucell Holland B.V. and Lonza Houston, Inc. (incorporated by reference to Exhibit 10.15 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on July 18, 2014).
4.8	Agreement between the Registrant and Prof. Jacob George, dated January 24, 2010, as amended on August 1, 2012 (incorporated by reference to Exhibit 10.16 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on June 6, 2014).
4.9	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).
4.10†	Master Services Agreement, effective as of January 30, 2015, by and between PPD Development, L.P. and the Registrant (incorporated by reference to Exhibit 4.18 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 25, 2015).
4.11#	Lease Agreement, dated as of June 10, 2016, by and between the Registrant and Darwish Shalom (incorporated by reference to Exhibit 4.19 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2018).
4.12†	Development, Commercialization and Supply Agreement, dated as of November 3, 2017, by and between the Registrant and NanoCarrier Co., Ltd. (incorporated by reference to Exhibit 4.20 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2018).
4.13†	Clinical Trial Services Agreement by and between the Registrant and the GOG Foundation, Inc. dated December 23, 2017 (incorporated by reference to Exhibit 4.21 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2018).
4.14†	Agreement by and between the Registrant and Biopharmax Group Ltd. dated June 1, 2016 (incorporated by reference to Exhibit 4.22 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2018).
12.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a).
12.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a).
13.1**	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.
15.1*	Consent of Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, Independent Registered Public Accounting Firm.

† Portions of this exhibit have been omitted pursuant to a grant of confidential treatment by the Securities and Exchange Commission and the non-public information has been filed separately with the Securities and Exchange Commission.

English summary of original Hebrew document.

* Filed herewith

** The certifications furnished in Exhibit 13.1 hereto are deemed to accompany this Annual Report on Form 20-F and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

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

VASCULAR BIOGENICS LTD.

By: /s/ Dror Harats

Dror Harats
Chief Executive Officer

Date: March 25, 2021

DESCRIPTION OF SECURITIES

The following description of the capital stock of Vascular Biogenics Ltd. (“us,” “our,” “we” or the “Company”) is a summary of the rights of our ordinary shares and certain provisions of our articles of association currently in effect. This summary does not purport to be complete and is qualified in its entirety by the provisions of our articles of association previously filed with the Securities and Exchange Commission and incorporated by reference as an exhibit to the Annual Report on Form 20-F of which this Exhibit 2.7 is a part, as well as to the applicable provisions of the Israeli Companies Law. We encourage you to read our articles of associations and applicable portions of the Israeli Companies Law carefully.

Authorized Capital**General**

Our authorized share capital consists solely of 150,000,000 ordinary shares, par value NIS 0.01 per share. All of our outstanding ordinary shares are validly issued, fully paid and non-assessable. Our ordinary shares are not redeemable and do not have any preemptive rights.

Registration Number and Purpose of the Company

Our registration number with the Israeli Registrar of Companies is 51-289976-6. Our purpose as set forth in our amended and restated articles of association is to engage in any lawful activity.

Voting Rights and Conversion

All ordinary shares will have identical voting and other rights in all respects.

Transfer of Shares

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

Election of Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for external directors.

Under our amended and restated articles of association, our board of directors must consist of not less than three, not including two external directors, but no more than nine directors (including the external directors). Pursuant to our amended and restated articles of association, other than the external directors, for whom special election requirements apply under the Companies Law, the vote required to appoint a director is a simple majority vote of holders of our voting shares, participating and voting at the relevant meeting. Each director will serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal by a vote of the majority voting power of our shareholders at a general meeting of our shareholders or until his or her office expires by operation of law, in accordance with the Companies Law. In addition, our amended and restated articles of association allow our board of directors to appoint directors to fill vacancies on the board of directors to serve for a term of office equal to the remaining period of the term of office of the director(s) whose office(s) have been vacated. External directors are elected for an initial term of three years, may be elected for additional terms of three years each under certain circumstances, and may be removed from office pursuant to the terms of the Companies Law. Following the adoption by the Company of certain reliefs provided under the Companies Law, the Company is exempt from the requirement to appoint external directors.

Dividend and Liquidation Rights

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

Pursuant to the Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, according to our then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of the distribution, or we may otherwise only distribute dividends that do not meet such criteria only with court approval. In each case, we are only permitted to distribute a dividend if our board of directors and the court, if applicable, determines that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

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

Exchange Controls

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of countries that are, or have been, in a state of war with Israel.

Shareholder Meetings

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be held no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to in our amended and restated articles of association as extraordinary general meetings. Our board of directors may call extraordinary general meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Companies Law provides that our board of directors is required to convene an extraordinary general meeting upon the written request of (i) any two of our directors or one-quarter of the members of our board of directors or (ii) one or more shareholders holding, in the aggregate, either (a) 5% or more of our outstanding issued shares and 1% of our outstanding voting power or (b) 5% or more of our outstanding voting power. One or more shareholders, holding 1% or more of the outstanding voting power, may ask the board to add an item to the agenda of a prospective meeting, if the proposal merits discussion at the general meeting.

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may be between four and 40 days prior to the date of the meeting. Furthermore, the Companies Law requires that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

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

The Companies Law and our amended and restated articles of association require that a notice of any annual general meeting or extraordinary general meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

Under the Companies Law and our amended and restated articles of association, shareholders are not permitted to take action via written consent in lieu of a meeting.

Voting Rights

Quorum Requirements

Pursuant to our amended and restated articles of association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. As a foreign private issuer, the quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or written ballot who hold or represent between them at least 25% of the total outstanding voting rights. A meeting adjourned for lack of a quorum is generally adjourned to the same day in the following week at the same time and place or to a later time or date if so specified in the notice of the meeting. At the reconvened meeting, any two or more shareholders present in person or by proxy shall constitute a lawful quorum.

Vote Requirements

Our amended and restated articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Companies Law or by our amended and restated articles of association. Under the Companies Law, each of (i) the approval of an extraordinary transaction with a controlling shareholder and (ii) the terms of employment or other engagement of the controlling shareholder of the company or such controlling shareholder's relative (even if not extraordinary) requires, the approval of our audit committee, our board of directors and a Special Majority, in that order. Under our amended and restated articles of association, the alteration of the rights, privileges, preferences or obligations of any class of our shares requires a simple majority vote of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting. An exception to the simple majority vote requirement is a resolution for the voluntary winding up, or an approval of a scheme of arrangement or reorganization, of the company pursuant to Section 350 of the Companies Law, which requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by voting deed and voting on the resolution.

Access to Corporate Records

Under the Companies Law, shareholders are provided access to: minutes of our general meetings; our shareholders register and principal shareholders register, articles of association and financial statements; and any document that we are required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Modification of Class Rights

Under the Companies Law and our amended and restated articles of association, the rights attached to any class of share, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our amended and restated articles of association.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If (a) the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (b) the shareholders who did not accept the tender offer hold 2% or more of the issued and outstanding share capital of the company (or of the applicable class), the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This requirement does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if, as a result of the acquisition, the purchaser would become a holder of more than 45% of the voting rights in the company, provided that there is no other shareholder of the company who holds more than 45% of the voting rights in the company, subject to certain exceptions.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) outstanding shares representing at least 5% of the voting power of the company will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (excluding the purchaser, controlling shareholders, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, by a majority vote of each party's shareholders, and, in the case of the target company, a majority vote of each class of its shares, voted on the proposed merger at a shareholders meeting.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same Special Majority approval that governs all extraordinary transactions with controlling shareholders. A Special Majority approval constitutes shareholder approval by a majority vote of the shares present and voting at a meeting of shareholders called for such purpose, provided that either: (a) such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such compensation arrangement; or (b) the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in the compensation arrangement and who vote against the arrangement does not exceed 2% of the company's aggregate voting rights.

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders of the target company.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the merging entities, and may further give instructions to secure the rights of creditors.

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

Anti-Takeover Measures under Israeli Law

The Companies Law allow us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. No preferred shares are currently authorized under our amended and restated articles of association. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our amended and restated articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Companies Law as described above in "Voting Rights."

Borrowing Powers

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

Changes in Capital

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

Warrants

As of the date hereof, warrants to purchase 4,234,313 ordinary shares were issued and outstanding at a weighted average exercise price of \$4.31 per ordinary share. The expiration dates of these warrants range from April 1, 2021 to June 25, 2022.

Transfer Agent and Registrar

Our transfer agent in the United States is American Stock Transfer & Trust Company, LLC.

Listing

Our ordinary shares are listed on The NASDAQ Global Market under the symbol "VBLT."

FOREIGN EXCHANGE CONTROLS AND OTHER LIMITATIONS

Israeli law limits foreign currency transactions and transactions between Israeli and non-Israeli residents. The Controller of Foreign Exchange at the Bank of Israel, through "general" and "special" permits, may regulate or waive these limitations. In May 1998, the Bank of Israel liberalized its foreign currency regulations by issuing a new "general permit" providing that foreign currency transactions are generally permitted, although some restrictions still apply. Under the new general permit, all foreign currency transactions must be reported to the Bank of Israel, and a foreign resident must report to his financial mediator about any contract for which Israeli currency is being deposited in, or withdrawn from, his account.

The State of Israel generally does not restrict the ownership or voting of ordinary shares of Israeli entities by non-residents of Israel, except with respect to subjects of countries that are in a state of war with Israel.

I, Dror Harats, certify that:

1. I have reviewed this annual report on Form 20-F of Vascular Biogenics Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 25, 2021

/s/ Dror Harats

Dror Harats

Chief Executive Officer

I, Amos Ron, certify that:

1. I have reviewed this annual report on Form 20-F of Vascular Biogenics Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 25, 2021

/s/ Amos Ron

Amos Ron
Chief Financial Officer

**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**

In connection with the Annual Report of Vascular Biogenics Ltd. (the “Company”) on Form 20-F for the period ended December 31, 2020 as filed with the Securities and Exchange Commission (the “Report”), I, Dror Harats, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 25, 2021

/s/ Dror Harats

Dror Harats
Chief Executive Officer

In connection with the Annual Report of Vascular Biogenics Ltd. (the “Company”) on Form 20-F for the period ended December 31, 2020 as filed with the Securities and Exchange Commission (the “Report”), I, Amos Ron, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 25, 2021

/s/ Amos Ron

Amos Ron
Chief Financial Officer

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-202463, 333-210583, 333-219969, 333-223232, 333-232391 and 333-240995) and on Form F-3 (No. 333-251821) of Vascular Biogenics Ltd. of our report dated March 25, 2021 relating to the financial statements, which appears in this Form 20-F.

Tel-Aviv, Israel
March 25, 2021

/s/ Kesselman & Kesselman

Kesselman & Kesselman

Certified Public Accountants (Isr.)

A member firm of PricewaterhouseCoopers International Limited
